IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

THE CITY OF HUNTINGTON,	:	Civil Action
Plaintiff,	:	No. 3:17-cv-01362
v.	:	
AMERISOURCEBERGEN DRUG CORPORATION, et al.,	:	
Defendants.	:	
CABELL COUNTY COMMISSION,	:	Civil Action
Plaintiff,	:	No. 3:17-cv-01665
v.	:	
AMERISOURCEBERGEN DRUG CORPORATION, et al.,	:	
Defendants.	:	

BENCH TRIAL - VOLUME 25
BEFORE THE HONORABLE DAVID A. FABER, SENIOR STATUS JUDGE
UNITED STATES DISTRICT COURT
IN CHARLESTON, WEST VIRGINIA

JUNE 11, 2021

APPEARANCES:

For the Plaintiff,
Cabell County Commission:

MR. PAUL T. FARRELL, JR.
Farrell & Fuller, LLC
1311 Ponc De Leon, Suite 202
San Juan, PR 00907

MR. ANTHONY J. MAJESTRO
Powell & Majestro
Suite P-1200
405 Capitol Street
Charleston, WV 25301

MR. PETER J. MOUGEY
Levin Papantonio Thomas Mitchell Rafferty & Proctor
Suite 600
316 South Baylen Street
Pensacola, FL 32502

MR. MICHAEL J. FULLER, JR.
Farrell & Fuller
Suite 202
1311 Ponce De Leon
San Juan, PR 00907

APPEARANCES (Continued):

For the Plaintiff,
Cabell County Commission:

MS. MILDRED CONROY
The Lanier Law Firm
Tower 56
126 East 56th Street, 6th Floor
New York, NY 1022

MS. PEARL A. ROBERTSON
Irpino Avin Hawkins Law Firm
2216 Magazine Street
New Orleans, LA 70130

MR. MICHAEL W. WOELFEL
Woelfel & Woelfel
801 Eighth Street
Huntington, WV 25701

MR. CHARLES R. WEBB
The Webb Law Center
716 Lee Street East
Charleston, WV 25301

MS. ANNIE KOUBA
Motley Rice
28 Bridgeside Blvd.
Mt. Pleasant, SC 29464

MR. MARK P. PIFKO
Baron & Budd
Suite 1600
15910 Ventura Boulevard
Encino, CA 91436

For the Plaintiff,
City of Huntington:

MS. ANNE MCGINNESS KEARSE
Motley Rice
28 Bridgeside Blvd.
Mt. Pleasant, SC 29464

MR. DAVID I. ACKERMAN
Motley Rice
Suite 1001
401 9th Street NW
Washington, DC 20004

MS. LINDA J. SINGER
Motley Rice
Suite 1001
401 Ninth Street NW
Washington, DC 20004

MS. TEMITOPE LEYIMU
Motley Rice
28 Bridgeside Blvd.
Mt. Pleasant, SC 29464

For the Defendant,
Cardinal Health:

MS. ENU MAINIGI
MS. JENNIFER WICHT
Williams Connolly
725 Twelfth Street NW
Washington, DC 20005

MS. SUZANNE SALGADO
725 Twelfth Street NW
Washington, DC 20005

MR. STEVEN R. RUBY
Carey Douglas Kessler & Ruby
901 Chase Tower
707 Virginia Street, East
Charleston, WV 25301

APPEARANCES (Continued):

For the Defendant,
Cardinal Health:

MS. ASHLEY W. HARDIN
MS. ISIA JASIEWICZ
Williams & Connolly
25 Twelfth Street, NW
Washington, DC 20005

APPEARANCES (Continued):

For the Defendant,
McKesson:

MR. TIMOTHY C. HESTER
MR. PAUL W. SCHMIDT
MS. LAURA M. FLAHIVE WU
MR. ANDREW STANNER
Covington & Burling
One City Center
850 Tenth Street NW
Washington, DC 20001

MR. JEFFREY M. WAKEFIELD
Flaherty Sensabaugh & Bonasso
P.O. Box 3843
Charleston, WV 25338-3843

APPEARANCES (Continued):

For the Defendant,
AmerisourceBergen Drug Corporation:

MS. SHANNON E. MCCLURE
MR. JOSEPH J. MAHADY
Reed Smith
Three Logan Square
Suite 3100
1717 Arch Street
Philadelphia, PA 19103

MS. GRETCHEN M. CALLAS
Jackson Kelly
P.O. Box 553
Charleston, WV 25322

APPEARANCES (Continued):

MR. ROBERT A. NICHOLAS
Reed Smith
Suite 3100
Three Logan Square
1717 Arch Street
Philadelphia, PA 19103

MS. ELIZABETH CAMPBELL
1300 Morris Drive
Chesterbrook, PA 19087

Court Reporter: Ayme Cochran, RMR, CRR
Court Reporter: Lisa A. Cook, RPR-RMR-CRR-FCRR

Proceedings recorded by mechanical stenography;
transcript produced by computer.

PROCEEDINGS had before The Honorable David A. Faber, Senior Status Judge, United States District Court, Southern District of West Virginia, in Charleston, West Virginia, on June 11, 2021, at 9:00 a.m., as follows:

THE COURT: Let me go over something here before we get on with the evidence.

We have the matter of scheduling the balance of the trial, and the plaintiffs have asked for a little more time. And I believe under all the circumstances that, that exist now that plaintiffs are entitled to a modest increase of their trial time.

So I plan to give you three more days, Mr. Farrell and Ms. Kearse.

The week of June the 21st that we had set aside for the break, or what we thought would be the end of the plaintiffs' case, is no longer available because of scheduling conflicts. So we'll still stand down that week.

So when we come back after that break on June 28th, which we had originally scheduled to begin the defendants' case, I'll give Monday through Wednesday, June 28th through 30th, to the plaintiffs to complete their case in chief.

If there are any motions at the conclusion of the plaintiffs' case that require oral argument, we can do that on Thursday, the 1st of July.

I would then stand down through the holiday weekend and begin the defendants' case on Tuesday, July the 5th. And we can make up for lost time in either of two ways.

I had set aside July 28th to 30th to try another case, and that case has been continued. So those days are available. If the parties still want to have a break in the middle of the defendants' case, we could simply add the extra time on at the end which would be the week of August the 15th. So I hope that takes care of those --

Mr. Schmidt.

MR. SCHMIDT: Yes, Your Honor. We have one witness issue, at least one witness issue.

Dr. Gilligan is our pain expert, standard of care expert. He was set to be up front in the rotation. He's on vacation that week of -- that Your Honor said we would start. He's on a two-week pre-planned vacation.

So if we could confer with our team and with the plaintiffs, but we'd like to, if it's possible, try to find a way to bring him that week we were planning on having the case even if it's agreeable to the Court on that Friday.

THE COURT: Well, yeah, if you can work that out, we could take his testimony on the 1st or 2nd of July.

MR. SCHMIDT: Okay. I think he's -- I don't have the dates in front of me, but the Thursday I think he has surgery. The Friday he might be able to do it. So let me,

let me --

THE COURT: Those two days -- under my revised schedule, those two days would be open and we could do it on Tuesday or Wednesday.

MR. SCHMIDT: I think he's got surgery one, but the other we'll check and see. And if we can do that, then we'll bring him then.

THE COURT: Okay. Well, we'll do that.

MR. SCHMIDT: Thank you, Your Honor.

THE COURT: Okay. Dr. Mohr.

MR. ACKERMAN: Thank you, Your Honor. We're bringing in Dr. Mohr now.

JAKKI MOHR, PLAINTIFFS' WITNESS, RESUMED THE WITNESS STAND

THE COURT: Dr. Mohr, it's my duty to tell you what you already know. You're still under oath.

THE WITNESS: Yes. Thank you. Good morning.

BY MR. ACKERMAN:

Q. Good morning, Dr. Mohr.

Okay. Dr. Mohr, you testified yesterday that you reviewed documents from defendants and opioid manufacturers in the course of forming your opinions; correct?

A. Yes.

Q. And do those documents form the basis of the opinions?

A. Yes, they do.

Q. Let's look at a few of those documents --

A. Sure.

Q. -- to start off.

MR. ACKERMAN: Can I have P-43195?

May I approach, Your Honor?

THE COURT: Yes.

THE WITNESS: Thank you.

BY MR. ACKERMAN:

Q. Dr. Mohr, I've handed you what is marked as Plaintiffs' Exhibit P-43195. Is this a document that you relied on to form your opinions?

THE COURT: Ms. Wicht.

MS. WICHT: Good morning, Your Honor. I'm sorry to stand up so early.

We do object. I understand that, from conversations, that Mr. Ackerman is not necessarily seeking to admit this document. However, we do want to lodge an objection.

It's a document that was produced by Endo, obviously not a party who is here in the courtroom. We have objections on the basis of authenticity and relevance. And although, of course, experts are permitted to rely on documents that are inadmissible, that's only the case where the document -- the probative value of the document substantially outweighs any prejudicial effect that it may have.

And our view is that -- our argument is that this document with questions about authenticity and relevance does not meet that standard of even sort of helpfulness to the trier of fact. And we object to it being used with Dr. Mohr even as -- even for her to sort of walk through it.

The document isn't otherwise admissible and, so, we don't think she should be permitted to sort of sit on the stand and read it into the record to the Court.

THE COURT: Where are you going to go with this, Mr. Ackerman?

MR. ACKERMAN: Sure. And, Your Honor, it is not my intention to have the witness read any documents into the Court.

These are documents that our expert witness relied on in forming the basis of her opinion. For Rule 703, an expert is entitled to rely on evidence even if it's inadmissible. And she will testify as to what the document is, whether she relied on it, and why she relied on it.

MS. MCCLURE: And, Your Honor, to, to not take away from anything Ms. Wicht said, but to underscore the fact that in a litigation, you would often have a witness on the stand where there would be a bucket of documents that either have been admitted or are likely to be admitted in the future.

In this unique instance, we're going to have a bucket

of documents that in its entirety or nearly -- in its entirety, I believe, are never going to be admitted in any vehicle in any, in any -- they will never be evidence in this case. Our witnesses have been gone. None of these documents have been offered with any of our witnesses even if they had been produced by any of the defendants in the case.

All of the documents are never going to be admitted in the case as evidence. So we believe that this is a unique circumstance.

And while 703 does allow that balancing act, plaintiffs have the burden to establish that the probative value substantially outweighs the prejudice associated with the fact that we have no ability to question Endo witnesses on this. There's no -- no Endo witness is going to be in the trial. That's going to be the same for Purdue, Teva, Janssen.

None of the documents you're going to see today with Ms. Mohr are ever going to be evidence in this case. So we think this is a unique scenario. And I recognize that this document is not being offered for ABDC, but I do want to underscore that this is going to be a recurring theme throughout this entire examination today.

MR. ACKERMAN: So, Your Honor, if I may respond.

First of all, on probative value, I will take the first

page of this document off.

The second page has Cardinal Health's logo and says "Marketing Programs Overview."

I don't -- this is a marketing witness. This document obviously has probative value. She is testifying that it is the basis of her opinion. The vast majority of these documents were produced by defendants. Nearly all of them will have defendants' logos on them.

MS. MCCLURE: Your Honor, the vast majority --

MR. ACKERMAN: She's entitled --

MS. MCCLURE: I'm sorry. I thought you were finished. I'm sorry.

MR. ACKERMAN: She's entitled -- the witness is entitled to explain the basis for her opinion. I don't intend to have her read documents into the record. There may be certain portions of documents that we point to, but it certainly can't be the case, Your Honor, that the witness is -- that somehow some unspoken prejudicial value that I don't think has really been explained --

THE COURT: Ms. McClure, do you want to respond to that?

MS. MCCLURE: My response is going to be to the statement that the vast majority of documents have been produced by defendants. There are 15 documents that Mr. Ackerman has identified for use with this witness.

Approximately half of them were not produced by the defendant distributors who are sitting in front of you today.

And, so, regardless of the fact that it has a Cardinal logo on it, as Mr. Ackerman has suggested, we are not in a position to authenticate these documents. There is a fundamental reliability concern with using these documents with the witness which were produced by defendants who are not here today.

MR. ACKERMAN: So, Your Honor, --

MS. MCCLURE: And I defer to Ms. Wicht.

THE COURT: Let me hear from Ms. Wicht.

MS. WICHT: I would just add, Your Honor, on the, the probative value of the documents, there's virtually no probative value to them, whether or not they have corporate logos on them or not.

This witness is not going to offer any opinions about whether any of the items that were -- that are discussed in these documents were ever sent to any Cabell/Huntington pharmacy, prescriber, anything else. She's not offering any opinion about the effects that any of these documents might have had on anyone; pharmacy, prescriber, patient, or otherwise.

So the -- I would submit, Your Honor, that all that could be done with these documents is a simple narrative

recitation of what they are and what they say. And that's something that this Court has already said is not helpful to the trier of fact in terms of expert testimony.

MR. ACKERMAN: So let me --

THE COURT: Well, let me --

MR. ACKERMAN: There is an important record point to be made that I think is probably the one Mr. Majestro is whispering in my ear.

(Pause)

MR. ACKERMAN: He had a different point which I'll relay as well.

The first point I want to make is that, Your Honor, as Your Honor is aware, this is a bellwether case in an MDL. All of these documents were produced by other parties in the MDL. Defendants had access to all of them. It's not like we're bringing out new documents. They've all been on our exhibit list. They are part of the overall opioid litigation.

Also, Rule 403 (verbatim) in a bench trial, Your Honor -- I just want to make my record -- has very limited value. And there are Fourth Circuit opinions on that.

THE COURT: Well, under Rule 403 the witness -- an expert witness is entitled to base her opinion on matters that are not admissible. And it doesn't make the -- it doesn't make the underlying documents admissible. But if

she relied on them in forming her professional opinion, it seems to me that I can let her talk about them. And then it's up to me to decide whether their prejudicial value outweighs their relevancy. So I'm going to let you go ahead.

MR. ACKERMAN: Thank you, Your Honor. I think it was Rule 703.

THE COURT: What did I say?

MR. ACKERMAN: You said 403.

THE COURT: 403 was up here on the screen.

MR. ACKERMAN: Well, here I am making trouble again.

THE COURT: You see how bad I am, Mr. Ackerman. Go ahead, please.

MR. ACKERMAN: All right. With that aside, I assume, Your Honor -- I'll ask this question at the outset. I assume that the defendants will object if I want to publish any of these documents that we go through.

MS. WICHT: Yes, Your Honor.

MS. MCCLURE: Yes, Your Honor.

THE COURT: Well, if she relied on them in forming her opinion, she can refer to them. But I'm not sure they need to be published, Mr. Ackerman. We'll cross that bridge when we get to it. Go ahead, please.

MR. ACKERMAN: All right. Thank you. I just

wanted to get the ground rules set at the start.

THE COURT: Yes.

BY MR. ACKERMAN:

Q. Okay. So with that done, Dr. Mohr, do you have P-43195 in front of you?

A. Yes, I do.

Q. Okay. And is this a document that you relied on to form your opinion in this litigation?

A. Yes, it is.

Q. And what defendant does this document relate to?

A. Cardinal Health.

Q. And how do you know it relates to Cardinal Health?

A. The cover email actually mentions Cardinal Health people by name. And it also has an attachment called "Cardinal Health Manufacturer Marketing Services." And the inside has the Cardinal Health logo on it.

Q. And what -- why did you rely on this document?

A. When companies engage in marketing, they actually have to market what it is that they're offering. And in this case, Cardinal Health was offering a paid service to the pharmaceutical manufacturers to perform marketing on their behalf.

So this is a brochure that details the types of marketing services that manufacturers, in this case Endo, paid for them to perform.

Q. And, Dr. Mohr, did you conclude whether Cardinal, in fact, provided marketing services to opioid manufacturers?

A. No. The document that I'm looking at right here is merely a marketing brochure. And, so, it's not clear that this work actually was ever done based on a simple brochure.

Q. Sure. And that was probably a bad question. Setting that document aside --

A. Uh-huh.

Q. -- in the overall penumbra of your work, did you conclude that Cardinal, in fact, provided marketing services to opioid manufacturers?

A. Yes, I did.

Q. Okay.

MR. HESTER: Let's go to the next document which is P-42701.

May I approach, Your Honor?

THE COURT: Yes.

THE WITNESS: Thank you.

BY MR. ACKERMAN:

Q. And, Dr. Mohr, the same set of questions here. Is P-42701 a document that you relied on to form your opinion?

A. Yes, it is.

Q. And what defendant does this document relate to?

A. McKesson.

Q. And what does -- why did you rely on this document?

A. Again, the title tells me that these are marketing services that McKesson is offering to the pharmaceutical manufacturers. It says "Brand Rx" where Rx is prescription, so this is the brand prescription marketing services that McKesson offers to the brand pharmaceutical manufacturers.

Q. Is there anything on the cover page of the document that you concluded indicated McKesson had a dedicated personnel who worked on manufacturer marketing?

A. Well, again, it says McKesson manufacturer marketing. In this particular case, most companies do have a team that performs this. I mean, there's a marketing department.

Q. And, Dr. Mohr, is this, like the other document, a brochure?

A. Yes, it is.

Q. Okay.

A. Yeah. Let me take that back. This is actually a PowerPoint presentation. And, so, this was prepared -- it's my, you know, educated opinion that this was delivered to one of the pharmaceutical companies to give them an overview of all these services. And, so, the second page actually is kind of like a Table of Contents of what those marketing services include.

Q. And, Dr. Mohr, putting this document aside, in the scope of your work did you conclude whether McKesson, in

fact, provided marketing services to opioid manufacturers?

A. Yes, they did.

MR. HESTER: Your Honor, objection. The term "opioid manufacturers" is not an appropriate term. These are not companies that only manufacture opioids. They're pharmaceutical companies that manufacture a range of products. It's a misleading question.

THE COURT: Well, can you rephrase your question to cover that, Mr. Ackerman?

MR. ACKERMAN: That sounded like a point for cross, but I'm happy to rephrase the question if it's the Court's preference. I think "opioid manufacturers" is a term that many witnesses have already used and --

THE COURT: Go ahead, Mr. Ackerman.

MR. ACKERMAN: I'll rephrase the question if that's the Court's preference.

BY MR. ACKERMAN:

Q. Dr. Mohr, did you, in fact, conclude that McKesson -- in the scope of your work, putting aside the document, did you conclude that McKesson, in fact, provided marketing services to pharmaceutical manufacturers who manufactured opioids?

A. Yes.

Q. Dr. Mohr, turn to slide 22 of this document.

A. Yes.

Q. Did you rely specifically on this page for any part of your opinion?

A. Yes. What was interesting to me about slide 22 is that it details that the services that McKesson offered would touch not only the retail pharmacists who were their direct customers in the supply chain, but they also offered services that would also touch and reach physicians and patients as well.

Q. You used the term "touch." Is that, is that your word?

A. It is my word. In marketing we refer to touch points. And touch points means that there's interaction or communication between two parties.

Q. But does the word "touch" also appear on this document?

A. Yes. It says, "McKesson manufacturer marketing touches key points in the healthcare continuum."

Q. So in your opinion, in this document was McKesson using marketing vernacular?

A. Absolutely.

Q. Thank you. You can put that document aside.

MR. ACKERMAN: Let's go to P-26091.

May I approach, Your Honor?

MS. MCCLURE: Your Honor, I maintain with respect to -- I'm sorry. With respect to this particular document, I note that there is -- there are many pages to this document. It's approximately, I don't know, 40 something

pages.

And contained within this document is a number of references to other companies under the AmerisourceBergen corporation umbrella. The defendant here in this particular case is AmerisourceBergen Drug Corporation, ABDC. We've heard it throughout the trial.

Throughout this document there are numerous mentions of other companies that are not part of ABDC. They are separately incorporated entities technically considered under the law to be affiliates. But liability against AmerisourceBergen Drug Corporation cannot be based on the conduct or alleged conduct of entities who are not parties to this case.

So I do, of course, note that this document is an ABDC produced document, meaning it was produced from ABDC's files. But as it comes to trial, I note that this document is full of many references to other entities that are not defendants in this case.

So, Your Honor, we believe liability against ABDC cannot be predicated under the laws of either Pennsylvania, which is where ABDC is located, the State of West Virginia, which is the forum state, the State of Delaware, which is where some of the other entities referenced throughout this document are incorporated or have their principal places of business.

And, so, we believe that the introduction of this document and its many, many references to non-ABDC defendants is prejudicial and we would object to its inclusion in this case.

THE COURT: Well, this is a document she relied on and I'll allow her to refer to it. And I think the point you raised is more appropriate for cross-examination than the exclusion of any reference to it.

So you can go ahead, Mr. Ackerman.

MR. ACKERMAN: Thank you, Your Honor.

BY MR. ACKERMAN:

Q. And, Dr. Mohr, I've handed you P-26091. Is this a document that you relied on in forming your opinion?

A. Yes, it is.

Q. Okay. And what defendant does this document relate to?

A. AmerisourceBergen.

Q. And why did you rely on this document?

A. As you can see on the cover sheet, they're requesting that the -- whoever these people are are called the suite of marketing services that these collective companies offer to the pharmaceutical manufacturers in order to have those services collectively reviewed by one of the top consultants in the world, McKinsey.

And they wanted to make sure that they could streamline all the offerings across these various companies in order to

both ensure consistent pricing to the manufacturers and to make sure that they were offering the most value to those manufacturers.

Q. Thank you. Now, Dr. Mohr, in the course of your work, putting this document aside, did you conclude whether AmerisourceBergen Drug Company's predecessor company, a company called Bergen Brunswig, provided marketing services to companies that manufacture opioids?

A. Yes.

Q. And, again, putting this document aside, did you also -- Dr. Mohr, did you also in the course of your work encounter evidence of any affiliates of AmerisourceBergen Drug Company providing marketing services to companies that manufacture opioids?

And I see that my colleague has stood up, so hold your answer until the objection.

THE COURT: This is your same objection?

MS. MCCLURE: It is my same objection. I understand Your Honor's ruling but feel the need to preserve the record on the fact that veil piercing has not been alleged in this case and liability cannot be based on affiliate conduct.

MR. ACKERMAN: It's the basis for her opinion, Your Honor. I'm sorry. Is the objection overruled?

THE COURT: You may proceed.

MR. ACKERMAN: Oh, thank you. I didn't hear you.

THE COURT: She's preserving her objection previously made, I believe, and it's overruled again and you may proceed.

MR. ACKERMAN: All right. Thank you.

BY MR. ACKERMAN:

Q. So, Dr. Mohr, let me repeat the question.

In the course of your work, did you encounter evidence of any affiliates of AmerisourceBergen Drug Company providing marketing services to pharmaceutical companies who manufacture opioids?

A. Yes.

Q. And who were the affiliates that, in your opinion, provided those marketing services?

MS. MCCLURE: Your Honor, may I just have a standing objection to this?

THE COURT: Yes.

MS. MCCLURE: Thank you.

THE COURT: Overruled. And you can have a continuing objection to this whole line of questioning.

MS. MCCLURE: Thank you, Your Honor.

BY MR. ACKERMAN:

Q. So, again, who were the AmerisourceBergen affiliates that -- who, in your opinion, provided marketing services to opioid manufacturers?

A. Xcenda, I hope that I'm saying that correctly, and Lash.

Q. Now, Xcenda is spelled X-c-e-n-d-a; is that correct?

A. Yes.

Q. And did you form an opinion as to what Xcenda is?

A. From what I could glean, they were a specific unit of AmerisourceBergen that provides a very sophisticated suite of marketing services to the pharmaceutical manufacturers.

Q. And when you say AmerisourceBergen, are you referring to AmerisourceBergen Drug Company or their parent company, AmerisourceBergen Corporation?

A. Yes. So the way I look at this and, in fact, the way I teach it in my classes, is most corporate umbrellas have subsidiaries that work underneath them. And the idea is collectively all of these units work together to elevate the profits of the total corporation.

And, so, in this particular case -- you know, I always use a pretty friendly example like Disney. So if we're talking about, you know, the Disney theme park is one unit. Disney cruises is another unit. Disney merchandise is another unit. And they all work collectively to make sure that the brand is able to deliver consistent performance over time. And in this case, the brand is AmerisourceBergen as the umbrella.

Q. Thank you. And you also mentioned Lash; is that

correct?

A. Yes.

Q. And what is -- I think it's called Lash Group. What is Lash Group?

A. It's another consulting unit that provided consulting services to the brand manufacturers for marketing.

Q. And how, if at all, did you conclude -- or, in your opinion, did you conclude whether Lash Group had any relation to AmerisourceBergen Drug Company?

A. If I recall correctly -- I need to look at my report -- but what my recollection is is that there were multiple documents that also said ABC on them or related to AmerisourceBergen.

Q. Okay. I think we're grabbing a copy of your report, so we'll go back to that.

A. Thank you.

Q. Sure. Would --

MS. MCCLURE: Your Honor, to the extent we're handing out Dr. Mohr's report, we would object to the introduction of this report or the use of the report other than to refresh Dr. Mohr's recollection. And she has referenced she would need to see a copy of her report, but we would object to it being handed out, introduced, or used for anything other than refreshing her recollection.

MR. ACKERMAN: Your Honor, that's all I was going

to do was refresh her recollection. And if I can just go on --

THE COURT: You can't refresh until it's not there. I mean, you can't refresh it --

MR. ACKERMAN: I have to ask the questions. I understand that. I didn't have a chance to do it yet.

THE COURT: Okay. Go ahead.

MR. ACKERMAN: Okay.

BY MR. ACKERMAN:

Q. Dr. Mohr, did you at one point have an opinion as to how Lash Group was related to ABDC?

A. Yes.

Q. And would reviewing your expert report refresh your recollection as to what you concluded?

A. Yes.

MR. ACKERMAN: May I approach, Your Honor?

THE COURT: You've got to ask her the question first.

MR. ACKERMAN: I asked her the question earlier, but I can ask her again.

THE COURT: "Did you at one point have an opinion as to how Lash Group was related to ABDC?" She said, "Yes." And then you asked her -- you, you have to show she can't remember before you can refresh her recollection.

MR. ACKERMAN: I'm sorry, Your Honor. I thought

she had already answered, she had already said she didn't remember, but I'll ask her.

BY MR. ACKERMAN:

Q. Dr. Mohr, how is Lash Group related to ABDC?

A. I have listed them as a sister unit to the company.

MS. MCCLURE: And, Your Honor, I believe she's answered the question, so there's no need to hand out the report. And I would request that the report be taken back from the clerk.

THE COURT: I think that's right. You can't use it.

MR. ACKERMAN: That's fine.

THE COURT: You can't refresh her unless she needs to be refreshed, Mr. Ackerman.

MR. ACKERMAN: I agree, Your Honor.

BY MR. ACKERMAN:

Q. Dr. Mohr, did you form an opinion that distributors' marketing was of recent vintage or had it been on-going for a while?

A. The earliest documents that I reviewed in my report were from 1995, and they carried through to approximately 2017. So that's a long period in my, my experience.

Q. Thank you.

MR. ACKERMAN: May I approach, Your Honor?

THE COURT: Yes.

BY MR. ACKERMAN:

Q. Dr. Mohr, I've handed you what's been marked as Exhibit P-8272. Is this a document that you relied on to form your opinions in this litigation?

MS. MCCLURE: So, Your Honor, with apologies, I am compelled to rise again. And this is a different type of objection, you'll be pleased to know, from the other ones.

As Your Honor is aware, the time period in this case, the relevant time period is from 2006 to 2018. Now, there have been instances where -- particularly with respect to Suspicious Order Monitoring Programs that had been in place pre-dating the 2006 time period, but carried over in their effectiveness into that effective time period of '06 to '18.

We've seen some older documents. We saw some yesterday with Joe Rannazzisi from 1998 about AmerisourceBergen's approval of its Suspicious Order Monitoring System.

However, here what we have, this is a document that was produced by Purdue. In the bottom right you can see the Purdue indicator. It is an internal memorandum to Purdue authored by someone G.R. Green. The date is in 1997.

And what this document appears to be is a summary of Purdue internal impressions of its relationships with four distributors.

And, so, there are significant authenticity concerns with this document. The relevance in the fact that it dates

from 1997 -- you'll note that Amerisource and Bergen are separate companies as referred to in this document. So this pre-dates the relevant time period by a substantial margin.

Moreover, this document is paradigmatic hearsay. The only reason that we would be looking at this document is, in fact, for what the, what the author of this memo, his personal impressions were of Purdue's relationships with these four distributors.

So there is significant reliability, authenticity, foundation, relevance concerns with this document in addition to, of course, the fact that it can't be admitted in the case. And I welcome my colleagues' comments as well.

THE COURT: Well, you're not offering it -- Ms. Wicht, do you want to say something?

MS. WICHT: I only was going to add one -- it's not an additional argument. I obviously agree with what Ms. McClure said, just a clarification on time period.

The time period that Ms. McClure identified is obviously correct. That's the time period for discovery. I just want to make clear that there's a disputed issue about what the relevant time period is for the claims in this case based on the statute of limitations that would actually be substantially shorter and even more recent than what Ms. McClure laid out.

MS. MCCLURE: And I join in Ms. Wicht's

clarification.

THE COURT: Well, if it's a document she relied on in forming her opinion and you're not offering it into evidence, I'll let you question her about it. I think all this goes -- you're not offering -- it all goes to the weight the Court is going to give her opinion. And it's a proper subject for cross-examination it seems to me.

MS. MCCLURE: Thank you, Your Honor.

MR. ACKERMAN: Thank you, Your Honor.

BY MR. ACKERMAN:

Q. Dr. Mohr, have you got P-8272 in front of you?

A. Yes.

Q. Is this a document that you relied on to form your opinion?

A. Yes, it is.

Q. And what defendant does this document relate to?

A. It relates to multiple defendants. It lists McKesson, Bergen Brunswig, Cardinal, as well as Amerisource.

Q. And as Ms. McClure stated, this is an internal Purdue memorandum; correct?

A. Yes.

Q. And, so, why did you rely on this document?

A. This document shows the important role of the distributors in the market success of the pharmaceutical manufacturers' products.

And, in particular, this was a critical time period, according to Purdue, in getting the wholesaler participation because the new programs that they were offering were going to be central to their success.

MR. HESTER: Object, Your Honor, on speculation. Move to strike that statement. The witness is speculating.

MR. ACKERMAN: Your Honor, I can cure that with one question.

MS. MCCLURE: And, moreover, Your Honor, we have an objection to the corporate conduct ruling that Your Honor made, ECF 1262, about the motives of any of the parties or non-parties.

THE COURT: Well, here again, she's explaining the basis of her expert opinion. And the weaknesses in this, which appear to me to be substantial, can be brought out on cross-examination. So I'll allow it. Go ahead.

BY MR. ACKERMAN:

Q. Dr. Mohr, was there something in this document that caused you to conclude that distributors played -- I think your word was an important part in the marketing of Purdue's opioid drugs?

A. Yes. There's details in the programs that the wholesalers were going to be offering. And the author of this document says in his own words, "Obstacles to our growth," meaning Purdue's growth, "lie predominantly with

our reluctance to spend money on these wholesaler programs."

The last sentence of the whole memo says, "With wholesaler friendly policies from us, we can expect programs that will be friendly and profitable to our company."

Q. Thank you. Dr. Mohr, in the course of your work, did you review any documents that referenced a glimmer button?

A. Yes. The document that I just reviewed mentioned a glimmer button.

Q. What is a glimmer button?

A. It appears to be an early precursor to what we now know as paid search. The idea was when a pharmacist searched for any of a competing product, the pharmacist could push a glimmer button on the distributor's website and Oxycontin advertising would appear.

Q. While Ms. Aguiniga is handing out this document, Dr. Mohr did you conclude whether any of the defendants or their predecessors here actually provided a glimmer button to Purdue in connection with marketing of Oxycontin?

A. Yes.

MR. ACKERMAN: May I approach, Your Honor?

THE COURT: Yes.

BY MR. ACKERMAN:

Q. Dr. Mohr, do you have P-43299 in front of you?

A. Yes.

Q. And is this a document that you relied on to form your

opinions in this case?

A. Yes.

Q. And what defendant does this document relate to?

A. Bergen Brunswig.

Q. And why did you rely on this document?

A. Again, this provides the detail to the client about how the glimmer button works. And, so, there were 25 targeted competitors by name. And during January, every pharmacist who ordered any of these 25 products could push the glimmer button and be encouraged to learn about Oxycontin.

Q. Thank you. And, Dr. Mohr, were you surprised by the timing of this document?

A. I was.

Q. Why?

A. Paper click advertising really didn't come in until the advent of the internet, you know, around 2000, 2001, 2002. And this was in 1995. And I thought these people were already inventing what we were going to be relying on in the future known as paper click advertising where you can specify a competitor's name and your ad will appear on the web browser.

Q. Dr. Mohr, let's put the documents aside for a minute. How do companies build a marketing strategy?

A. A marketing strategy is a strategic process that companies undertake. Much like building any sort of a

business strategy, this is one component of a business strategy. And most companies use a sequence of steps in that process.

The first step most companies use -- and this is what we teach and it's kind of classic in all the marketing books -- is you start with what's known as a situation analysis where there is a very thoughtful and thorough scan of what's happening in the competitive landscape to understand the opportunities and threats and trends that are happening broadly in society and in the economy. That's a very important aspect because staying current with trends is a key part of successful marketing.

The next process is to really do research to understand customer buying motivations, customer barriers to purchase, customer triggers.

The next step, then, is to do a segmentation analysis. Not all customers are created equal is the way we teach it in marketing, and some customers are more important than others based on their volume of purchase or based on their propensity to purchase. That's known as segmentation.

After we segment the markets, then each category of customers would receive a unique messaging strategy. For example, if you're parents when you buy a car, you have different purchase needs than if you're a young, single male who's buying a car.

This is known as value proposition design. And every segment gets a different value proposition to address their buying triggers.

There are a couple more steps in the process and I don't want to bore anybody. I live and die by this and I find it fascinating.

So then the company, based on that solid research, actually builds the marketing components. And those are known as the four Ps. And I'm not going to talk about the four Ps now because I'm sure that is too much detail.

And the final step in any marketing strategy is measuring the effectiveness of the marketing strategy. We sometimes call this return on investment. So if you spend a certain amount of money on marketing, you do expect to earn a return on that, as you would any business investment. So all companies measure the sales lift attributable to their marketing strategy.

Q. So let's walk through each of those six steps.

A. Let's do.

Q. The first step that you mentioned, Dr. Mohr, was situational analysis; is that correct?

A. Yes.

Q. And do you have an opinion as to whether any of the distributor defendants or companies affiliated with them engaged in situational analysis in connection with the

description of opioid -- or distribution of opioid medications?

A. Yes.

Q. Okay. And which companies did you determine participated in situational analysis?

A. Based on my recollection of my report, I clearly remember McKesson and Xcenda.

Q. Let's go with the next document, 42508.

MR. ACKERMAN: May I approach, Your Honor?

THE COURT: Yes.

BY MR. ACKERMAN:

Q. Dr. Mohr, is this a document that you relied on to form your opinion?

A. Yes, it is.

Q. And why -- what defendant does this document relate to?

A. This document is titled "McKesson Patient Relationship Solutions." It is for Janssen.

And what you will see, as I flip through this document, the second page -- I don't know which numbers I'm supposed to use, but it actually says "Consumer Marketing." So the minute I see the word "marketing," I kind of look at it.

And then it says "Behavioral Experts" and "Data Analytics." And those are all components of marketing, so I felt like I had to dig in a little further.

Q. I'm sorry. Where are you looking in the document?

A. I am -- after the one that says "Introduction," I am then on the next page right at the bottom.

Q. Oh, I see.

A. I'm sorry.

Q. The bubbles at the bottom?

A. Yes. Thank you.

Q. Okay. And, Dr. Mohr, was there a particular portion of this document that led you -- that formed the basis of your opinion that McKesson engaged in situational analysis?

A. Yes. If you turn to the little numbers on the right that says 6 on the Number 6 page -- I think I'm supposed to use the numbers on the right.

Q. Yes.

A. Okay.

Q. And what is that page titled?

A. It says "Market Update." And, again, not all companies use the word "Situation Analysis," so somebody that's experienced in marketing kind of knows what a situation analysis includes.

And what we see on the first set of this whole slide deck is industry data, as I just mentioned a good situation analysis does. And this one in particular is comparing how customers, patients abandoned their prescriptions based on the co-pay amount on the next page, the market update, the graph.

And what you'll see is that the Nucynta abandonment data from McKesson is compared to the market abandonment data for non-McKesson pharmacists.

I don't think that was the best explanation. Please forgive me. But, anyway, it's giving market data. Let me just leave it at that.

Q. That's the portion you relied on; right?

A. Yes, one portion. But then I continued to see how they used that market data in their recommendations.

Q. I understand. We may get to that.

A. Okay.

Q. Dr. Mohr, you stated that you had concluded that Xcenda had conducted situational analysis as well; is that correct?

A. Yes.

Q. And what was the basis for your opinion that Xcenda was involved in situational analysis?

A. Xcenda also provided competitive overviews and industry trends to various brand manufacturers in order to help them develop their marketing strategies.

Q. Let's put this exhibit in a different pile because I want to come back to it.

Dr. Mohr, -- I'm sorry. Before we move on from situational analysis, is there a specific example you can recall of Xcenda providing situational analysis?

A. No. I would need to reference my report for that. I'm

sorry.

Q. Okay. And would reviewing your report refresh your recollection as to any specific examples?

A. Yes, it would.

MR. ACKERMAN: Your Honor, may I give her the report? Thank you.

MS. MCCLURE: And, Your Honor, I'm sorry. Ms. -- Dr. Mohr can, of course, have the report, but I do object to the report being handed to the Court. This is a refreshing recollection, so the report should be taken back from the deputy clerk. Thank you.

BY MR. ACKERMAN:

Q. Okay. Dr. Mohr, take a moment to review your report. Let us know when you have reviewed it and whether your recollection is refreshed.

A. Yes. I just pulled one page out at random because there's so much in here.

Q. Okay. So can you -- let me ask the question again. Can you recall any specific examples that form the basis of your opinion that Xcenda was involved in situational analysis with respect to the marketing of prescription opioids?

A. Yes. Xcenda did quite a bit of work that included collecting data on payers and analyzing payers. It did quite a bit of work on looking at patient and physician

perceptions of opioids. And all of that would fall in the situation analysis to leverage that data in order to dial in a marketing strategy.

Q. Thank you. Dr. Mohr, let's talk about market research next. How is market research different from situational analysis?

A. Market research is generally very -- generally very focused on specific types of customers in terms of understanding what their needs are, whereas a situation analysis is very broad and might focus on things like the economy, cultural trends, competitive trends, whereas the market research is really focused on understanding the buying motivations and triggers for specific customer purchase groups.

Q. And did you form an opinion as to whether any of the distributor defendants or companies affiliated with them engaged in market research or manufacturers of opioids?

A. Yes, I did.

Q. And which, which ones?

A. I do recall Xcenda specifically.

Q. I'm going to hand you -- do you recall whether McKesson was engaged in market research for manufacturers of pharmaceutical opioids?

A. Yes, yes, I do recall.

Q. Okay. Let's go with the next document, 42911.

MR. ACKERMAN: May I approach, Your Honor?

THE COURT: Yes.

BY MR. ACKERMAN:

Q. Dr. Mohr, do you have P-42911 in front of you?

A. Yes, I do.

Q. And is this a document that you relied on to form your opinion?

A. Yes, I did.

Q. And why did you rely -- first of all, what defendant does this document relate to?

A. McKesson.

Q. And why did you rely on this document?

A. This document is titled "Summary of Qualitative Research Conducted Among Family Physicians." So -- and it's prepared by the Pharmaceutical Partners Group of McKesson.

So that means that this group was performing the research for their pharmaceutical partners, meaning the brands or the manufacturers.

Q. What's the date of this document?

A. Let's see. October, 2000.

Q. And for what -- for what pharmaceutical manufacturer was this research performed?

A. Purdue.

Q. Did you determine whether McKesson provided any recommendations based on their research?

A. Yes.

Q. And did those recommendations factor into your opinions in this case?

A. Yes.

Q. Okay. Would it be typical for companies engaged in marketing research to provide opinions based on the market research they have conducted?

A. Absolutely.

Q. And what, what recommendation -- what portion of this document led you to conclude that McKesson had provided recommendations to Purdue?

A. So the third page, so the little numbers on the right, Page 3, has the Table of Contents. And Page 4 says that they have a summary of recommendations on Page 4.

Q. And then if you look at Page 5, is that a page that you also relied on?

A. Yes.

Q. Okay. And what is, what is the title of that page?

A. "Inclusions and Recommendations."

Q. And did you find any recommendations in this document that were specific to prescription opioids?

A. Yes. The things that stuck out to me were specific recommendations regarding the messaging that physicians, family physicians in particular would likely respond to in terms of increasing their likelihood of prescribing -- in

this case, I think it was Oxycontin. Let me double-check that. Yes, Oxycontin.

Q. So can you point specifically in P-42911 to the recommendations that you're referring to that you considered in connection with your opinion?

A. Yes. Recommendation Number 5 I recall quite specifically because it says that the research showed that family physicians were worried about prescribing non -- narcotics long-term; that they would exacerbate addiction concerns.

And, so, the specific recommendation that McKesson offered for this was that Purdue should consider sponsoring pain management conferences or lectures by opinion leaders to focus physician attention on addiction and tolerance issues.

Q. And would you look at Paragraph 9. And is Paragraph 9 a recommendation that you considered in connection with forming your opinions in this case?

A. Yes.

Q. Okay. And why did you, why did you rely on Paragraph 9?

A. Again, a key part of marketing is connecting the dots between the research and then the actual marketing strategy that's implemented.

And in this particular case, the research showed that

family physicians do distinguish long-acting agents such as Oxycontin, and they are reserved for patients with acute pain.

And the idea was that the family doctors didn't believe that Oxycontin suffered -- I'm using the words here in the report -- from the stigma of other narcotics.

And the recommendation, then, was that Oxycontin should focus on these issues in their marketing material to increase the use of Oxycontin and position it as a safer narcotic alternative.

Q. And those words that you've just used, do they appear in the document?

A. Yes, Recommendation Number 9.

Q. Thank you. Put that document aside. Let's move on to the next step of building a marketing strategy which you said is segmentation analysis; is that correct?

A. Yes.

Q. And do you have any opinion as to whether any of these defendants or companies affiliated with them engaged in segmentation analysis with respect to the marketing of pharmaceutical opioids?

A. Yes, I do.

Q. And which companies?

A. Xcenda.

MR. ACKERMAN: Let's get the next document,

please, P-4333.

May I approach, Your Honor?

THE COURT: Yes.

MS. MCCLURE: And while they're handing that out, Your Honor, I just wanted to make sure that my standing objection relates not just to a particular document but to the whole issue. Thank you.

THE COURT: Okay.

BY MR. ACKERMAN:

Q. Dr. Mohr, do you have P-43333 in front of you?

A. Yes, I do.

Q. And is this a document that you relied on to form your opinion?

A. Yes, I did.

Q. And what defendant does this relate to?

A. Xcenda.

Q. And why did you rely on this document?

A. Because it talks specifically about a segmentation strategy used to develop a targeted list. And, again, this is just squarely one of the most important parts of marketing.

MS. MCCLURE: So, Your Honor, I apologize, but Mr. Ackerman said what defendant does this relate to. Xcenda is not a defendant in this case.

THE COURT: That's well-taken. Go ahead, Mr.

Ackerman.

MR. ACKERMAN: Yes. So let me clean that up, Your Honor.

BY MR. ACKERMAN:

Q. Dr. Mohr, which company was performing the segmentation analysis you've just described?

A. Xcenda. It does say on here -- it calls it AmerisourceBergen Consulting Services.

Q. Thank you. Okay. And for what product was -- did you conclude the segmentation -- the payer segmentation had been performing?

A. This one is for Fentora.

Q. And is Fentora an opioid, to your knowledge?

A. Yes.

Q. Dr. Mohr, are you familiar with something called the 80/20 rule?

A. Yeah, of course.

Q. And would you explain to the Court what the 80/20 rule is?

A. Yeah. So when we as marketers segment markets, we again -- maybe I'm saying live and die too much. We live and die by the 80/20 rule.

And what this means is that 20 percent of a group of customers accounts for 80 percent of the purchase volume in that category.

And this is heuristic or rule of thumb. We require industry data to determine who those heavy users are of a particular product category. And the goal of marketing is to focus on that group of heavy users because simply by marketing to them, we can capture 80 percent of the revenue in the market. So it drives efficiency in marketing.

Q. And, Dr. Mohr, did you see any evidence -- or in reviewing P-43333, did you see any evidence of application of that marketing concept?

A. Yes, I did. It was quite interesting to me that the detail in this document says that the segmentation was on targeted payer plans. So this was focusing on the payers.

And the way that we would look at payer plans from a segmentation perspective is in terms of the covered lives under that insurance plan.

And in this particular case, the recommendation was to focus on the top 38 plans to cover the majority of covered lives through the insurance policies in the marketing strategy for Fentora.

Q. Thank you. Let's turn to value proposition design. And since it's been a little while since you explained it, can you just briefly explain what a value proposition design is?

A. Uh-huh. Value proposition design is the message strategy that is used to address the buying trigger of the

identified customer.

Q. And, Dr. Mohr, in the course of your work, did you form any opinion as to whether any of the defendants or companies affiliated with them engaged in value proposition design with respect to the marketing of pharmaceutical opioids?

A. Yes, I did.

Q. And which companies?

A. AmerisourceBergen, Xcenda.

Q. Let me just make that clear.

A. I know. I'm confused now. It's like I -- go ahead.

Q. Was it AmerisourceBergen Drug Company or was it Xcenda?

A. It was Xcenda.

Q. Thank you. Let's -- and is that opinion based on documents that you reviewed?

A. Yes. All my opinions are based on documents that I reviewed.

MR. ACKERMAN: Let's go to P-43335 please.

May I approach, Your Honor?

BY MR. ACKERMAN:

Q. Dr. Mohr, I've handed you a document marked P-43335. Do you have that in front of you?

A. Yes, I do.

Q. Okay. Is this a document that you relied on to form your opinion?

A. Yes, I did.

Q. And why did you rely on this document?

A. Again, if you look at the title, it says that this is the presentation of the payer value story development proposal, so payer value story.

And what you see is that this is from Xcenda, Tim Regan, AmerisourceBergen Consulting Services. And what's interesting in here is they go through the various ideas that they're developing to craft a value proposition for, if I recall correctly, it was hydrocodone. Let me just see here.

Q. So if you would turn -- actually, if you look at the page -- there's a page that says "produced natively." Do you have that as Page 5?

A. Yes, I do.

Q. And then there's a following page?

A. Yes.

Q. And did you rely on that page in determining whether the services that were described in this document were related to prescription opioids?

A. Yes. So the PowerPoint presentation is for Teva and it's for a couple drugs, Nuvigil, if I'm saying that correctly, and AD hydrocodone.

Q. Thank you. In your opinion, is this a particularly sophisticated type of marketing?

A. Yes, it is. Many companies just do what we call spray

and pray. They just blow an advertising message out and hope that people will respond to it.

But by going through these careful sequence of steps to do the market analysis and the research and the segmentation and the value proposition, that optimizes the chance that when you actually get to the communication, you're going to have an impact.

And, so, this is quite sophisticated, but this is not the most sophisticated value proposition design that I saw.

Q. What was the most sophisticated one that you saw?

A. I had never seen this in my experience as a marketing professor, so it stood out to me. It's called a triangulated value proposition. And these are the words in the document.

And it said, "We're simultaneously going to optimize the payer value story with the physician value story with the patient value story and hit the sweet spot of the three of those in our value proposition design." So it was a triangulated value proposition.

Q. And which company prepared that triangulated value proposition?

A. Xcenda.

Q. So, now, let's turn to marketing plan.

A. Okay. Let's do.

Q. And, Dr. Mohr, I assume that when the rest of us who

don't study marketing for a living think of marketing, is marketing plan generally what we think of?

A. No. Generally, you think of the things that you love to hate like annoying commercials or annoying salespeople or wondering if you're really getting a good deal on a rebate or if they just raised the price before they gave you the rebate. So most people think only of that front-facing marketing.

Q. So you mentioned the four Ps of a marketing plan. What are the four Ps of a marketing plan?

A. Yeah. So, again, marketing is a very systematic approach to optimizing revenue in the marketplace. And the four Ps include the products that are being developed and sold. And even retailers have a product mix that they select. And, so, even if you're not a manufacturer, you still have a product strategy.

The price that you charge for those goods is critically important in signaling value and signaling the customers you're going after.

The promotion mix is a separate part of marketing, all those things you love to hate that I just told you about.

And then the fourth P is place. And place means distribution channel. Place is the place where customers gain access to the product and service.

Q. Dr. Mohr, were you able to form an opinion as to

whether any of the defendants or companies affiliated with them were involved in connection with the mix of promotions for pharmaceutical opioids?

A. Yes, I did.

Q. And what is that opinion?

A. Many of the services they offer did focus on the promotion mix.

Q. And is that true for all of the -- AmerisourceBergen, McKesson, and Cardinal?

A. Yes, it is.

Q. So let's first look at the first three documents we took out today, the overview documents. Do you have those in front of you?

A. Let me grab them.

Q. Sure. And, actually, let's just look at one of them as an example. Let's look at P-43195 which is the Cardinal overview.

A. Thank you.

Q. And, Dr. Mohr, what is a fee-for-service offering?

A. Most marketing services are performed on a fee-for-service basis. And, so, if you're an advertising agency, you submit a proposal to perform services and the client pays you for those services rendered.

Q. And did you form an opinion as to whether any of the defendants or companies affiliated with them provided

fee-for-service marketing to manufacturers of pharmaceutical opioids?

A. Yes, I did.

Q. And which defendants provided fee-for-services?

A. All three of them.

Q. Okay. And just looking at this list, or this document that's in front of you, 43195, does this -- did you rely on this document in connection with concluding whether Cardinal offered fee-for-service programs?

A. Yes, I did.

Q. And where in this document or how -- why did you rely on this document?

A. What you'll see is that the services that Cardinal is offering to the pharmaceutical manufacturers lists the price for each service.

So, for example, if you wanted, as a pharmaceutical manufacturer, to subscribe to the First Script service, you would pay $15,000 for that service. That includes notifying the pharmacy chain of the deal information. And these would include service flashes and facets.

And, so, all of these were communication tools that the manufacturer could purchase from Cardinal Health. There are a number of other services listed as well. If you'll allow me to go on, one thing that's --

Q. Let's keep going because I want to make sure that -- I

know you've got time constraints and we want to make sure --
A. Thank you.
Q. You're welcome.
MR. ACKERMAN: Let's get the next document.
BY MR. ACKERMAN:
Q. Dr. Mohr, did you, in the course of forming your opinion, conclude whether any of the defendants offered savings cards with respect to pharmaceutical opioids?
A. Yes, I did.
Q. And are savings cards a form of promotion?
A. Yes. Anything that's designed to give a financial incentive to a consumer is considered a sales promotion. And that falls into the promotion mix.
Q. And what is a savings card?
A. In this particular case, a savings card was designed to help pay for the co-pay on the prescription. But we know things like coupons and rebates would be the equivalent of what we see in consumer marketing.
MR. ACKERMAN: May I approach, Your Honor?
THE COURT: Yes.
BY MR. ACKERMAN:
Q. Dr. Mohr, I'm handing you what is P-43331. Dr. Mohr, is this a document that you relied on to form your opinion?
A. Yes, it is.

Q. And what defendant does this document relate to?

A. Cardinal Health.

Q. And why did you rely on this document?

A. Because this document lists a savings card. I just want to refresh my mind for a minute on this one.

Q. If you look about halfway down the page, Dr. Mohr.

A. Yes. This was a Butrans email. And it says "Butrans savings card." Thank you. It took me a while to see it because often times I see the visual image of the actual savings card in my brain that I've seen before. So --

Q. And to your understanding, is Butrans an opioid?

A. Yes, it is.

Q. And which company manufactured Butrans?

A. Purdue.

Q. Dr. Mohr, if we can put that document aside.

Did you form an opinion as to whether any of the defendants or companies affiliated with them provided marketing services in connection with product launches of opioid products?

A. Yes, I did.

Q. Okay.

MR. ACKERMAN: Let's get the next document, 42605. May I approach, Your Honor?

THE COURT: Yes.

BY MR. ACKERMAN:

Q. Dr. Mohr, I've handed you what's P-42605. Is this a document that you relied on to form your opinions?

A. Yes, it is.

Q. And, Dr. Mohr, what defendant does this document relate to?

A. McKesson.

Q. And why did you rely on this document?

A. This is a communication that went out from McKesson to its Retail Weekly Wire which is a type of email subscription that the pharmacist would subscribe to, and it essentially gives the highlights of the week. This is dated January 13th, 2011. So communication with customers of marketing.

Q. And if you would turn to Page 3, Dr. Mohr.

A. Yes.

Q. And specifically beginning about halfway -- or about halfway down on the page, did you rely on any portion of Page 3 in connection with your opinion?

A. Yes, I did.

Q. And can you explain to the Court which portion of this page you relied on?

A. Yes. This is a service that McKesson offers called Rx Focus Launch. And it's actually an auto ship program where auto ship means that for a targeted pharmacist, McKesson would actually auto ship newly launched drugs into the

marketplace.

Q. And does -- did this document give any indication of to whom McKesson would be auto shipping drugs?

A. Yes. The first bullet says that 3,000 customers -- in this case, it would be pharmacies -- have been identified for this auto ship because they are high dispensers of similar medication.

Q. And, Dr. Mohr, would this be -- seem to you to be an application of the 80/20 rule?

A. Yes.

Q. Put that document aside, Dr. Mohr. Let's go back to the one I said put in a separate pile, 42508, if you would, please.

A. Yes, just one minute. My piles are getting a little confused. Just bear with me.

Q. You got nothing on the Judge. He's got piles on top of his piles.

A. His desk looks like my office. Okay, I found it.

Q. All right, great. You have 42508 if front of you?

A. Yes, I do.

Q. And to refresh everybody, this is the McKesson document entitled "Nucynta & Nucynta ER 2012 Data Review." Is that right?

A. Yes.

Q. And to your understanding, is Nucynta an opioid

medication?

A. Yes, it is.

Q. And is it a prescription opioid medication?

A. Yes.

Q. Okay. On the cover of this page does it indicate -- does it indicate whether McKesson provided savings cards for Nucynta?

A. Yes. In fact, there is an image of this on the cover that is prepared by McKesson, a Nucynta savings card.

Q. And if you would turn to slide 11, please.

A. Slide 11?

Q. Yes.

A. Yes. That's -- got it.

Q. And is this a slide that you relied on in connection with your opinion?

A. Yes. This one essentially says that there's going to be a $25 savings program, which means when the patient presents the card, they just pay $25 for the co-pay.

Q. And, Dr. Mohr, did this slide describe other promotional programs for Nucynta?

A. Yes. We see additional detail here. The slide deck provided also details regarding other types of programs, including pharmacy intervention coaching.

Q. Before we get to that, Dr. Mohr, --

A. Yes.

Q. -- would you turn to Page 31, please.

A. Yes. This is another program update, another form of sales promotion.

Q. Okay. Hold on. Let me ask the question first before you answer.

Is -- beginning at Page 31 and a few pages following through, say, about Page 39, are these pages that you relied on in connection with forming your opinions in this case?

A. Yes.

Q. And why did you rely on these pages?

A. Because they talk about a sampling program. And sampling is a critical part of that promotion bucket to encourage consumers to try the product. And in this case, it says "Nucynta 10 Free Pills Program."

Q. Did you say 10 free pills?

A. This one is 10 free pills. I did see others for three free pills.

Q. Okay. And to be clear, that phrase "10 free pills" appears on Page 31; correct?

A. Yes, consistently through the next pages because we see a program overview that compares the sales lift attributed to the sampling program.

Q. And is that -- are you describing what is reported on slide 34?

A. Yes, I am.

Q. Thank you.

A. What we see is that sampling is one of the most effective marketing tools. And in this case, it increased average monthly claims on Nucynta of 198 percent from the prior year.

Q. So, Dr. Mohr, I want to take a break from documents for a moment and I want to clarify one thing.

Are you today offering any opinions concerning the effectiveness of the opioid marketing that you observed?

A. No.

Q. And was that part of your assignment for this case?

A. No.

Q. Have you conducted any kind of statistical analysis to determine the effect of distributors' marketing on sales?

A. No.

Q. Have you conducted any kind of statistical analysis to determine whether the distributors' marketing increased demand for opioids?

A. No.

Q. And have you conducted -- and you didn't conduct any of that analysis because that wasn't your job; right?

A. Correct.

Q. What were you asked to do in connection with forming opinions for this litigation?

A. I was asked to determine whether or not the

distributors engaged in marketing of opioids.

MR. ACKERMAN: Let's go to the next document, 43234.

May I approach, Your Honor? We're almost done.

BY MR. ACKERMAN:

Q. Dr. Mohr, do you have document 43234 in front of you?

A. Yes, I do.

Q. And is this a document that you relied on to form your opinions?

A. Yes, I did.

Q. And what defendant does this document relate to?

A. The defendant in this particular case is ABC.

Q. And why did you rely on this document?

A. Because this is a summary of a sales promotion offer that ABC is receiving for fentanyl.

Q. Okay. And was there any indication -- and, so, if this was a summary of a sales promotion offer, what role did it play in forming your opinion?

A. In this particular case, it's very important that the distribution channel members, distributors' efforts are tightly aligned with the brand manufacturers' efforts.

And in this particular case, to align those efforts, fentanyl, Mallinckrodt was offering ABC a 15 percent payout for the sales of fentanyl that shipped out of their -- that

they received as orders.

And what struck me was the volume of money involved. In this particular case for a particular time period, ABC was already eligible for $10.6 million in the payout. And the email is encouraging them to put fentanyl in a primary position on their ordering platform so that they could actually get a 20 percent payout rate, in which case they would receive $20 million.

Q. Thank you. Dr. Mohr, let's put that document aside. Did you form any opinion as to whether conducting outreach to pharmacies concerning pharmaceutical opioids is a form of marketing?

A. Yes.

Q. And what is that opinion?

A. Yes, that distributors engaged in outreach to pharmacies.

Q. Let's go back again to the McKesson Nucynta document, 42508. Do you have that?

A. Yes, I do.

Q. Okay. And was there a particular part of this document that you relied on in connection with forming that opinion?

A. Yes. I had mentioned the important role of marketing strategy previously. And on Page 44, this particular document goes into more strategic aspects of how to encourage customers to use the product.

Q. And, in fact, if you turn to Page 47 --

A. Yes.

Q. -- did you refer, or did you rely on this slide in connection with your opinion?

A. Yes. So Page 47 talks about how we use those key patient contact points again where the contact is a touch point. And we talk about the role of the physician -- not "we." In this particular case, McKesson talks about the role of the physician, the pharmacy, and the patient in optimizing engagement is the words that they use here which, again, is marketing jargon.

MR. ACKERMAN: May I approach, Your Honor?

THE COURT: Yes.

BY MR. ACKERMAN:

Q. Dr. Mohr, I've handed you what's marked as P-43300. Do you have that document in front of you?

A. Yes.

Q. And is this a document that you relied on to form your opinions in this case?

A. Yes.

Q. And what defendant does this document relate to?

A. Bergen Brunswig.

Q. And, again, that's the predecessor of ABDC; correct?

A. Yes.

Q. And why did you rely on this document?

A. This document shows that Bergen would be able to do a mailing to -- it's called an educational mailing. And an educational mailing is for the -- excuse me. It's by PlusCare which is the managed care division of Bergen Brunswig is what it says.

And they were going to increase the education of pain management to 1,800 community pharmacists with a mailing that included six particular types of informational content. And, again, educate and inform means generally awareness, and it's one of the key roles and key objectives of marketing.

Q. And was this -- you, you talked about two marketing concepts today; the 80/20 rule and you've talked about making sure that strategies are aligned; right?

A. Uh-huh.

Q. Did you, in forming your opinions, see any evidence of those two concepts in this document?

A. Yes. In this particular case, they were focusing on high prescribers of opioids and territories, and making sure that those high prescribers were aware that the Bergen Brunswig pharmacy affiliates, Good Neighbor Pharmacies, or their captive pharmacies, have Oxycontin available.

Q. And the words "high prescribers," are those your words or are those the words that appear in the document?

A. Those are the words in the document.

Q. And when you said have Oxycontin available, are those your words or are those the words that appear in the document?

A. They're in the document.

Q. Thank you. Let's put documents aside for a minute. I want to ask you about a couple more marketing concepts and then we'll wrap up.

What is a patient adherence program?

A. A patient adherence program from a marketing lens is something that's designed to make sure that people utilize the product once they purchase it.

Q. And did you form any opinion as to whether any of the distributors or their affiliates were engaged in patient adherence programs in connection with -- related to prescription opioids?

A. Yes.

Q. Which defendants?

A. My recollection is that they all did.

Q. What about sales force training? What is sales force training?

A. As I mentioned earlier, one of the things that's really central to marketing is the role of selling in the promotion mix. And certainly in this industry, the role of selling is critically important.

Q. And, Dr. Mohr, did you form any opinion as to whether

any of the distributors or their affiliates were involved in sales force training?

A. Yes.

Q. And which ones?

A. It was the unit of ABC Xcenda.

Q. Okay. What's thought leadership?

A. Thought leadership refers to gaining credibility and trust through authoring articles that portray an image of expertise.

Q. Outside of the pharmaceutical industry, just in the world at large, can you give us some examples of thought leadership?

A. Yes, I can. One of the most important things that's been happening right now during COVID when customers can't -- haven't been able to go to stores to buy products, we see companies like Nike building out a platform on apps for motivating people to exercise and giving them nutrition tips. These are completely independent of marketing any Nike product whatsoever.

Q. Did you form an opinion as to whether any of the distributors or their affiliates were engaged in thought leadership with respect to prescription opioids?

A. Yes.

Q. And which ones?

A. All three did various versions of thought leadership.

Q. And can you, sitting here, recall any examples of thought leadership that formed the basis of your opinion?

A. Yes. So thought leadership often times includes providing education and training. And all three distributors offered trade shows at which various target customers could attend to be educated on new drugs and new trends.

Q. And did any -- what about continuing medical education classes? Did that factor into your opinion?

A. Yes. The -- I'm trying to recall which distributors specifically offered continuing medical education. I would have to look at my report for that. But at least two of the three I recall did offer continuing medical programs.

Q. Let's just make sure so the record's clear. Can you look at your report and then -- would looking at the report refresh your recollection?

A. Yes.

Q. Okay. So can you look at the report and let us know which defendants, in your opinion, provided continuing medical education classes concerning prescription opioids?

A. ABC Specialty Group, Xcenda, ABC's Imidex unit, and McKesson and Cardinal Health are all listed in that section of my report.

Q. Thank you. And, again, your conclusions were based on?

A. Evidence that I reviewed, documents that I reviewed.

Q. Did you form an opinion as to whether any of the distributors or companies affiliated with them authored articles in medical journals concerning opioids?

A. Yes.

Q. And which, if any, of the distributors or their affiliates were involved in authoring articles?

A. It was the ABC affiliate Xcenda.

Q. Okay. And, again, what was the basis for that opinion?

A. Extensive documentation regarding their role.

Q. What is a key opinion leader?

A. In marketing, an opinion leader is somebody who's relied on as a trusted expert. And, as a result, they're viewed as highly credible.

Q. And, Dr. Mohr, did you form an opinion as to whether any of the distributors or their affiliates were involved in identifying or coordinating with key opinion leaders with respect to prescription opioids?

A. Yes.

Q. And outside of the pharmaceutical industry, can you provide an example of the use of key opinion leaders?

A. Yes. It's quite common that companies hire opinion leaders to help engage their audience. This is really popular right now in the beauty and fashion industry where we see social media influencers being used quite heavily by makeup brands.

In addition, in the outdoor industry it's quite common to have brand ambassadors who essentially if they're out training or engaging in outdoor activities will use social media to give us a shout-out for why they're using a particular brand. And it gives more credibility because it's considered to be authentic and unbiased.

Q. And I don't remember whether I asked this question. Let me ask it again. Did you form an opinion as to when -- whether any of the distributor defendants or companies affiliated with them were involved in identifying or coordinating with key opinion leaders?

A. Yes.

Q. And which, if any, of the companies or their affiliates?

A. I'm sorry, my memory is running a little thin right now. I would need to refresh my memory so I'm 100 percent accurate.

Q. Okay. Would it refresh your recollection to look at your expert report?

A. Yes.

MR. ACKERMAN: Your Honor, may she look at her expert report?

THE COURT: Yes.

THE WITNESS: My report references ABDC.

BY MR. ACKERMAN:

Q. Is it ABDC or one of their affiliates?

A. My report says ABDC.

Q. Okay.

MR. ACKERMAN: I'm mindful of the time, Your Honor. I am almost done, but I don't know whether we want to --

THE COURT: Well, I'll let you finish your direct if you can do it in five minutes.

MR. ACKERMAN: It might take eight, but I'll do my best.

THE COURT: Well, we better take a break then. We'll be in recess for ten minutes.

You can step down during the break, Dr. Mohr.

THE WITNESS: Thank you.

(Recess taken at 10:29 a.m.)

THE COURT: Dr. Mohr, if you'll resume the witness stand, please.

All right. Mr. Ackerman.

BY MR. ACKERMAN:

Q. All right. Dr. Mohr, let's continue to talk about public relations. Is public relations a form of marketing?

A. Yes. Public relations falls in that promotion bucket along with the other tools we've talked about.

Q. And let's just define it so everybody knows what we're talking about. What do you mean when you refer to public

relations?

A. Public relations is the part of marketing that's designed to create favorable impressions among a broad variety of stakeholders including media, society, government, et cetera.

Q. And putting aside pharmaceutical industry, just talking about the industry at large --

A. Uh-huh.

Q. Are you generally aware whether companies conduct public relations through trade organizations?

A. Yes. Trade organizations are a very important part of public relations because oftentimes an industry will share common issues and by having a collective approach in addressing those issues, the whole industry benefits.

Q. Can you provide an example?

A. Yes. For example, it's fairly common in the, again, outdoor industry. If companies are concerned that engagement of society generally is going down, then they might form an industry association that markets collectively the goal and benefits of getting families outside.

So, there are two groups that I'm thinking of in particular. One is called Go Boating and the other is called Go RVing. And they are industry associations designed to get more people going outdoors because, guess what? When they go outdoors, they need to buy gear.

Q. Dr. Mohr, first of all, are you aware as to whether the defendants here were members of a trade organization?

A. Yes, they were.

Q. And what was that trade organization?

A. The current name of it is the HDA, the Healthcare Distribution Alliance.

Q. And, Dr. Mohr, did you form an opinion in connection with this case as to whether the defendants conducted public relations related to prescription opioids through their Trade Association, the HDA?

A. Yes.

Q. And what was the basis for your opinion?

A. I reviewed internal documents that were from all three companies regarding the expectations they had for the HDA to act on their behalf.

Q. Thank you. We're getting close to the end now, Dr. Mohr. We've looked at, I'd say, roughly 15 documents today. Do those documents represent the sum total of your reliance materials?

A. No.

Q. Do you have any estimate of how many documents you relied on in forming your opinion?

A. I relied on hundreds of documents, tens of thousands of pages.

Q. If we went through every document while you were on the

witness stand, how long would that take?

A. I love data science and so, I did some math and, in this particular case, my estimate with tens of thousands of pages, if we spent about six minutes per document, we would probably be here a week to go through all the documentation.

Q. And so, Dr. Mohr, are the documents that we looked at today representative of other internal documents that are referenced in your report as the basis for your findings.

MR. HESTER: Object as vague, Your Honor.

THE COURT: Overruled. She can answer.

BY MR. ACKERMAN:

Q. Let me ask the question again, Dr. Mohr. Are the documents that we looked at today representative of the other internal documents that you relied on as the basis for your findings?

A. Yes. And if I may, I just think that they are very average collection in the sense that I saw some that were, you know, less and more sophisticated than this. So, this -- I tried to pick, you know, kind of a representative set.

Q. Thank you. Dr. Mohr, to summarize, is it your opinion -- or it is your opinion that distributors or companies affiliated with them were engaged in the marketing of opioids, correct?

A. Yes.

Q. And in forming that opinion did you rely on documents

showing sophisticated marketing?

A. Yes. This was some of the most sophisticated marketing that I've seen.

Q. And in forming your opinion did you rely on documents showing distributor involvement at multiple levels of the marketing process?

A. Yes, I did.

Q. Now, just to be clear, distributors don't manufacture the opioids, correct?

A. Correct.

Q. But in forming your opinion, did you draw any conclusions as to why the distributors would participate in the marketing of prescription opioids?

MR. HESTER: Object as calling for speculation.

THE COURT: Wait a minute.

MS. WICHT: And join the objection, Your Honor. That's okay. Go ahead.

MS. MCCLURE: Join and contrary to the corporate conduct ruling that Your Honor has previously made regarding motives and corporate conduct with respect to experts in general.

THE COURT: Well, I will sustain that, the objection to that one, Mr. Ackerman. That gets into the realm of speculation and I will sustain the objection.

MR. ACKERMAN: I did ask, Your Honor, whether she

had formed -- okay. Let me ask the question again.

BY MR. ACKERMAN:

Q. Did you come -- did you, Dr. Mohr, form any opinions as to why the distributors participated -- as to whether the distributors reaped any benefit from participation in the marketing of opioids?

MR. HESTER: Same objection, Your Honor.

MS. MCCLURE: Join.

THE COURT: I'll overrule that one. You can answer that one, if you can, Dr. Mohr.

THE WITNESS: Could you read the question back, please?

BY MR. ACKERMAN:

Q. Sure. Did you, Dr. Mohr, form any opinions as to whether the distributors reaped any benefit from their participation in the marketing of prescription opioids?

A. The evidence that I reviewed, the documents suggested that the distributors benefited financially from the incremental lift due to their marketing programs.

MS. MCCLURE: Your Honor, I move to strike that testimony as contrary to Dr. Mohr's prior opinion that she had no opinion whether distributors' alleged marketing had any impact on sales or had -- and had no marketing causation opinion. That response directly contradicted her prior opinion and the assurances the plaintiffs have offered

regarding this witness.

MR. ACKERMAN: So, Your Honor, first of all, I think they can explore that on cross. I don't think there's any contradiction at all. She did testify that she viewed representations in documents concerning the effective marketing programs. She's not offering any causation opinion.

THE COURT: I will -- I'll deny the motion. I think you're correct. It can be explored on cross.

MR. ACKERMAN: Thank you. Can I have a moment, Your Honor?

(Pause)

MR. ACKERMAN: I have no further questions, Your Honor. We'll pass the witness.

THE COURT: All right. Thank you, Mr. Ackerman. You go first?

MS. MCCLURE: I do, Your Honor. However, we have a matter we would like to discuss with the Court and think it would be appropriate at this time to request that the Court excuse Dr. Mohr for the period of time addressing that matter.

THE COURT: All right. This is things that happen in trials, Ms. -- Dr. Mohr, so if you could just wait in the witness room across the hallway, we'll call you back in a minute.

(Pause)

THE COURT: All right. Ms. McClure.

MS. MCCLURE: Thank you, Your Honor. At this time, I will say that my -- I expect my colleagues to chime in after I address the Court, but we do move to strike the entire testimony of Dr. Mohr. What we have just heard is that the distributors engaged in marketing. That is the sum total of Dr. Mohr's opinion.

Marketing is not a tort. If it were, Dr. Mohr wouldn't have a job. Companies in America would not be able to continue to operate.

Dr. Mohr has clearly stated that she offers no opinion that any of this marketing impacted sales for prescription opioids at all. She has no marketing causation opinion. She has not attempted to link any conduct between the distributors' marketing and sales anywhere, let alone in Huntington-Cabell.

Moreover, Dr. Mohr in her deposition clearly testified that none of the marketing materials she viewed did she evaluate them for whether they were false or misleading. She testified she has no opinion that any of the materials she reviewed was a lie.

Now, the -- so what we are left with here is basically so what? Helpfulness to the trier of fact is the touchstone of Rule 702, as Your Honor well knows from the *Koger v.*

Norfolk Southern Railway opinion.

The existence of marketing proves nothing. Plaintiffs' marketing theory as articulated in their complaint is that the manufacturers' deceptive marketing caused harm in these jurisdictions, that they falsely convinced prescribers of the safety of opioids. That's at the third amended complaint, Paragraph 374.

Merely showing that distributors marketed without tying any of that to an increase in sales or to any false or misleading conduct does nothing. It is not enough. It is not helpful.

To be clear, Your Honor, there are no other witnesses that the plaintiffs will be offering on anything having to do with marketing. Drs. Lembke, Kolodny and Keyes have already been prevented by Your Honor's order to testify regarding marketing causation. So, those marketing causation experts are out.

Dr. Mohr has simply testified if distributors say they didn't market, that's not true. They did. That has no connection to the issues that are before Your Honor.

And so, the opinions here have no relevance to the issues in this case. Your Honor will have no reason to return to any of these opinions in evaluating any of the evidence as a fact-finder.

Rule 702 applies in bench trials. That's the *UGI*

Sunbury case, *Kumho Tire*, as well, the decision from Justice Scalia. There's simply no fit to Huntington-Cabell. There is no relevance to this testimony and we request that it be stricken.

Of course, we are prepared to cross Dr. Mohr, if need be, but in a case where we have timing concerns, to us, we've spent two hours-plus on an expert related to proving that defendants, if Your Honor were to accept the testimony, marketed, which simply is irrelevant.

THE COURT: Ms. Wicht? Mr. Hester?

MS. WICHT: Your Honor, certainly, we join everything that Ms. McClure said. What I would add to that, Your Honor, is that I believe that although it was potentially disguised in the manner of the questioning, I think that what we have just seen is a paradigmatic example of what the Court excluded, which is an expert simply coming in reciting what is in documents; in this case, documents that are not admitted into evidence and never will be admitted to evidence. She's simply come in and sort of recited her review of the documents and what she saw.

The fact that she then -- the only thing she adds to that is that she says this is what the document said and it's my opinion that that is marketing. I would respectfully submit that that is not an opinion; that, in addition to all the grounds that Ms. McClure said, is not an

opinion that is helpful or meaningful to the Court. And we would also request that she be excluded on the basis that she simply provided prohibited factual narrative.

THE COURT: Mr. Hester?

MR. HESTER: Your Honor, my colleagues have stated it well. I would just add that it's really a truism that companies in this country and the global economy market services and that's all that Dr. Mohr has testified to. Her opinion really is nothing more than the opinion that the companies are engaged in marketing.

She specifically disavowed any opinion on any effect on sales of prescription opioids. She specifically disavowed any analysis as to whether the marketing activities increased demand. So, we're left merely with a truism and we submit it's not relevant to the Court. It's not relevant to any disputed issue in this case that companies engage in marketing full stop.

And so, I wanted to underscore, we are under time pressure here. It will take us a little while to sift through what she said because, as Ms. Wicht points out, she's gone through a number of documents. It's going to require us to work through those documents and to undermine them through cross examination. We're prepared to do that, but we submit it's not sensible as an allocation of the Court's time to proceed any further with this subject

matter.

THE COURT: Mr. Ackerman, do you want to respond to that?

MR. ACKERMAN: Yes, Your Honor. A couple of things, Your Honor. Number one, you've already denied that motion with respect to this witness, so I think this is just reiterating arguments that you have already rejected.

Number two, the defendants are the ones who seek to blame manufacturers in this case. They have a witness list that includes 130 people. Nearly all of them are may-call witnesses. And it includes representatives from each of the opioid manufacturers that they intend to put on by designation.

In the opening, Your Honor, and this is -- I don't know who had this because it was just e-mailed to me because this was not raised with us in advance, but one of the defendants said here's what the evidence will show if the issue of marketing becomes one we have to focus on at trial. The issue -- the evidence will show that our primary customers, our pharmacies, have platforms that allow manufacturers to pass along the information.

Their -- the opening statements focused on opioid manufacturers. Defendants' case is likely to focus on opioid manufacturers.

We have a witness who has put forth an opinion as to

what the distributors did. They are free to cross her on that opinion. If -- the Court has already decided that this evidence is helpful and I don't think the defendants have raised anything new here, Your Honor, that hasn't been raised before.

THE COURT: Well, as I understand it, the principal theory of the plaintiffs' case is that the manufacturers created demand and flooded the market with product and we have a little bit of evidence here that these defendants participated in that. I think it goes to the weight rather than the admissibility and I'm not going to strike her testimony. We'll see what happens on cross examination.

MR. ACKERMAN: Thank you, Your Honor.

THE COURT: That will determine what weight, if any, I give to her testimony.

MR. ACKERMAN: Thank you, Your Honor.

THE COURT: Do you want to bring her back in?

(Pause)

THE COURT: You may cross examine, Ms. McClure.

MS. MCCLURE: Thank you, Your Honor.

CROSS EXAMINATION

BY MS. MCCLURE:

Q. Good morning, Dr. Mohr.

A. Hello.

Q. Briefly, I want to return to your background that you discussed with Mr. Ackerman. To be clear, you did not specialize in healthcare or pharmaceutical marketing for any of your degrees, correct?

A. Correct.

Q. And you don't specialize in the pharmaceutical supply chain, correct?

A. Correct.

Q. You have no experience specific to the pharmaceutical marketing industry; is that correct?

A. Correct.

Q. You agree that there are unique features and aspects to the pharmaceutical industry, right?

A. I do cite those in my report, yes.

Q. One of those is the applicability of the Controlled Substances Act?

A. Yes. I do cite that in my report.

Q. You are not an expert on the Controlled Substances Act, right?

A. No.

Q. And another unique aspect of the pharmaceutical industry is the role of the Food & Drug Administration, or the FDA, right?

A. Correct.

Q. And you've never worked at the FDA?

A. No. I have not worked at the FDA.

Q. And you've never published on the FDA's regulation of prescription medication or language and labeling regarding prescription medication?

A. No, I have not.

Q. And you don't consider yourself to be an expert on indications for prescription opioids or the labeling that goes on the outside of the package or with -- that is distributed with a prescription medication, including opioids?

A. What was the question?

Q. I'm sorry. You don't consider yourself an indication on -- indications [sic] for which prescription opioids can be prescribed?

A. I'm not an expert on that.

Q. Okay. And you're not an expert on the labeling that the FDA permits to be distributed with a prescription, including a prescription opioid, correct?

A. No. I have not claimed that expertise.

Q. Okay. And another unique aspect of the pharmaceutical industry is the role of the physician in prescribing medication, correct?

A. Correct.

Q. So, this is not an industry where we're talking -- your opinions are not talking about marketing directly to

consumers, correct?

A. Are you talking about physicians or consumers?

Q. I'm actually -- I switched my question to consumers. You're not talking about distributors marketing to consumers, right?

A. Do you mean patients?

Q. Correct.

A. I did just review the touch points that distributors had with patients in the documents that we looked at here this morning.

Q. But the individual in the marketing -- in the pharmaceutical industry, you're not an expert in the role of the physician in that industry and how physicians make the decisions on prescribing, correct?

A. I am not an expert in how physicians make decisions on prescribing.

Q. Okay. And you've never personally attended a medical or a pharmaceutical education course?

A. No, I have not.

Q. A different unique aspect that we haven't yet talked about of the pharmaceutical industry is the role of the pharmacy benefit manager, called a PBM, right?

A. Correct.

Q. And you would agree that that makes the pharmaceutical industry an even more complicated industry than we've

already talked about, correct?
A. Yes. I do detail the role of the PBMs in my report.
Q. But you've never worked for a PBM, correct?
A. No. I'm a marketing professor.
Q. Okay. And you've never worked for a pharmaceutical manufacturer or distributor, right?
A. No, I have not.
Q. And have you ever published any articles on pharmaceutical distributors?
A. I have not published on pharmaceutical distributors.
Q. Or spoken at a conference on pharmaceutical distributors?
A. I have not spoken at a conference on pharmaceutical distributors.
Q. And you've never spoken on a conference of MARC that relates to the marketing of controlled substances, right?
A. I've not spoken at a conference on marketing of controlled substances.
Q. And I believe that you've published a couple of articles that do relate to the pharmaceutical industry, but neither of those relate to controlled substances, correct?
A. Correct.
Q. In fact, prior to being retained in this case, is it true that you've never reviewed any materials sent by a wholesale distributor to a pharmacy, correct?

A. Correct.

Q. And you testified on direct, I believe that the words that you used were, I'm an academic nerd?

A. Yes, I am.

Q. I -- I share that affinity with you. And that the way you learned about the pharmaceutical industry for this case included buying books and reading articles written by experts in the pharmaceutical industry, right?

A. Correct.

Q. All of the materials that related specifically to the defendants in this case, ABDC, McKesson and Cardinal, those materials were provided to you by counsel for plaintiffs, Motley Rice, correct?

A. Yes.

Q. And you've talked about how you reviewed a lot of documents, but you did not request access yourself to a document database or a repository, correct?

A. I did not request access to a database.

Q. Okay. So, shifting to distributors, you understand that the technology and information systems that distributors have are for all products they ship and all types of medications, not just for prescription opioids, correct?

A. I do understand that.

Q. And you're aware that distributors distribute/ship many

other medications well outside of pharmaceutical opioids like insulin, heart medication, et cetera, right?

A. Yes, I do.

Q. And you have no awareness of the percentage of opioids versus non-opioids that distributors have shipped nationwide or into Huntington-Cabell, correct?

A. No, I was not asked to do that analysis.

Q. So, that was not within the scope of your task?

A. Correct.

Q. Okay. So, we're talking about marketing and I believe in your report you outline two different kinds or types of marketing. One is marketing that differentiates between competitors, correct?

A. Yes.

Q. Called brand marketing?

A. Yes.

Q. Okay. And then there's another type of marketing that your report identifies as attempting to expand the demand for the entire market, which you call primary demand, right?

A. Yes. That's called indirect marketing.

Q. Okay. So, brand marketing is the type of marketing where you're asking a consumer or, in this case, a physician -- or, I'm sorry, a pharmacist, to choose your product over another company's product, correct?

A. I wasn't sure of the question.

Q. Well, that's because I bumbled it. So, brand marketing is the type of marketing where you're asking the purchaser, whoever that may be, to choose your product over someone else's product or all of these products over here, right?

A. Correct.

Q. Okay. So, for example, you sit down at a diner. I've already decided that I want to order a soda and the question is Pepsi versus Coke. Is that an example of brand marketing?

A. Technically, the decision of Pepsi versus Coke is brand marketing, but the way Coke distribution works is they actually are available on an exclusive basis with different types of stores. So it's not a really --

Q. So, maybe Coke was a bad example. Let's say I'm in a place and they have two things for me to choose from, RC Cola or Pepsi?

A. Yeah. When you go to the grocery store and you're at the point of purchase, then you are making a decision about a brand at the point of purchase.

Q. Okay. And so, it's still a single point of purchase? There's one drink being sold. The question is which brand is going to be the drink, correct?

A. Yes. You're oversimplifying, but that's fine.

Q. I know I am and I know that you are a Regents Professor and know a lot more about marketing than I do, but I want to

make sure that I and the Court have a distinction between this kind of marketing and then the other kind.

So, let's talk about market expansion. So, that strategy is aimed at the whole product class. That's market expansion, right?

A. I didn't use the word market expansion. I called it indirect marketing, which is designed to grow sales for the product class as a whole.

Q. Okay. So, that would be an example of I'm walking down the street. It's a hot day. I'm not generally a soda drinker, but there's a soda -- one of those people standing outside of a convenience store, right, and they're just advertising the fact that the convenience store sells cold beverages. That benefits all the makers of cold beverages, right?

A. Yes. I see your point.

Q. And I know it's oversimplified.

A. I see your point. I think I would go back to my Industry Trade Association when we try to get more people to go outdoors. It's designed to grow sales for the industry as a whole.

Q. Okay. So, the two main types of marketing that we've discussed here, is it fair to say that many of them can be categorized into either brand marketing or market expansion?

A. Do you mean you and I talking or do you mean all day?

Q. Today. Your testimony today.
A. Okay. I did talk about both types of marketing without using that -- those words, so I'm glad you've pulled them out of my report.
Q. Okay. So, let's also talk about just some basics about prescription opioids. You know that prescriptions are written by doctors?
A. I do know that.
Q. Okay. And do you know what detailing is? I think you talked about your father, who is in the prescription industry and so you --
A. No. My father is a physician.
Q. Oh, I'm sorry.
A. Yeah.
Q. So, your father was visited by detail people, I think you said, correct?
A. Correct, yes. Yes.
Q. And a detail person, that's when a pharmaceutical representative goes to visit a doctor to encourage that doctor to prescribe that manufacturer's products; is that right?
A. Correct.
Q. And you are not aware of the distributors in this case ever engaging in detailing of physicians, correct?
A. Yes. We did talk about this morning in my evidence

that we looked that the distributors did role play and train the detailers for the manufacturer salespeople.

Q. That's not my question. My question was you're not engaged -- you're not aware of distributors engaging in the detailing of a physician; in other words, a distributor doing that detailing at the physician's office like your father's office?

A. No. Distributors don't do that.

Q. Thank you. And, of course, you know that in order to get a prescription opioid legally dispensed a patient has to present a valid prescription written by a medical professional, right?

A. Yes.

Q. Okay. And many of the marketing activities you've described in your report are ones that you believe are directed to pharmacies, correct?

A. Many of them are.

Q. Okay. And you, of course, understand that pharmacists can't themselves prescribe?

A. I do understand that.

Q. And so, you also understand that without a prescription, a medication that a distributor ships to a pharmacy is simply going to stay on that shelf until a patient comes in with a valid prescription written by a medical professional and requests that to be filled, right?

A. If you're understanding if I understand that, I do understand that.

Q. Okay, thank you. And you understand that the FDA is ultimately responsible for providing a manufacturer with approval to manufacture any drug, including opioids?

A. Yes.

Q. And you understand that the FDA actually has to approve the language that goes on that medication, the communication to the patient that comes with the medication as FDA approved?

A. I do understand that.

Q. And you understand that the label's language is all that is permitted to be said about a product's risks and benefits?

A. I do understand that.

MR. ACKERMAN: Objection, Your Honor. That called for a legal conclusion. It's also arguably outside the scope.

MS. MCCLURE: I'm asking about --

THE COURT: Overruled. Go ahead.

MS. MCCLURE: Thank you.

BY MS. MCCLURE:

Q. I want to be clear about something given the topic of your testimony today. It's essentially whether certain activities do or do not constitute marketing, correct?

A. No. I wouldn't characterize it that way. I was asked did distributors engage in marketing.

Q. Okay. Then I'll use your formulation. You are here today to discuss the answer to the question did distributors engage in marketing, correct?

A. Correct.

Q. Okay. You were not asked to evaluate the veracity, the true or falseness, of the marketing messages themselves in any way, correct?

A. No, I was not.

Q. And so, you have not identified anything that is false or misleading in the documents you reviewed to prepare your report, correct?

A. I did not address the truth or veracity of the marketing documents.

Q. And, in fact, you have no reason to believe that any of the statements in the distributors' marketing were a lie, correct?

A. I'm just a little confused about what I'm being asked. So, the marketing messages --

Q. So, let me -- let me rephrase it. You -- you did not evaluate the truth or veracity, falsity, misleading-ness at all of any of the materials you reviewed? That wasn't your task, right?

A. Yeah. If you're asking if the marketing messages were

a lie, I didn't look at the veracity of the marketing messages.

Q. Okay. So, you don't have any opinion here today that anything was false or misleading, correct?

A. Correct. I have no opinion about that.

Q. Thank you. And, Dr. Mohr, you reviewed -- I'm sorry. Let me start that again.

You did not attempt to disentangle the effect of distributors' marketing activities, as you call them, from any other factors to determine the impact on sales of prescription opioids, correct?

A. The way that that would be done is through a mathematical model. I did not do a mathematical model.

Q. Is that model called an econometric study?

A. Yes, it is.

Q. Okay. And you were not asked to do that mathematical model in this case, correct?

A. No.

Q. Meaning no, you were not asked to do it; am I correct in this statement?

A. I was not asked to do it.

Q. Thank you.

Shifting to Huntington and Cabell, who are the plaintiffs here in this case, you have not similarly conducted any specific analysis to address the effect of

distributors' marketing on any pharmacy on the distribution of prescription opioids in Huntington or Cabell, correct?

A. Correct.

Q. And, in fact, you have not seen any documents that are specific to West Virginia or these two specific jurisdictions, correct?

A. Correct.

Q. And you have not studied the pharmacies in the West Virginia area in preparing your report?

A. I did not study the pharmacies.

Q. And you do not know whether the ordering function at a pharmacy is something done by the pharmacists in the Huntington-Cabell pharmacies that are at issue here or something done by non-pharmacist personnel in those pharmacies, correct?

A. Correct.

Q. And you don't know, in fact, if a person orders at all, as opposed to an automated inventory management system, correct?

A. Correct.

Q. And you cannot point me to any instances where a distributor defendant in this case advertised a manufacturer's opioid products to a retail pharmacy in Huntington or Cabell, correct?

A. Correct.

Q. Okay. Let's talk about some specific documents. The first one I want to talk about is the P-43299. That is the glimmer button, two-page e-mail document. Let me know when you've had a chance to look at that.

A. Yes, I have it.

Q. Okay. Now, this is a document from 1995, correct?

A. It's dated December 21st, 1995.

Q. And it relates to a company called Bergen Brunswig, right?

A. Correct.

Q. And so, you've talked about digital marketing and a glimmer button that pops up when a pharmacist is entering the system to order a prescription opioid, correct?

A. Yes. I'm sorry if I used the wrong word. This talks about a glimmer button, but digital marketing wasn't even a thing until much later.

Q. Okay. So, the point that I'm asking you about is, so it says glimmer button will show up when a pharmacist calls for a targeted competitor prescription opioid. Pushing the button will then reveal information on OxyContin to the pharmacist; right, that's what it says?

A. That's what it says.

Q. So, if a pharmacist goes to order a competitor product, that is when this glimmer button appears and encourages the pharmacist to instead choose a different product, right?

A. Correct.

Q. But you know that the glimmer button is only going to pop up if the pharmacist is already ordering a prescription opioid, correct?

A. Yes. One of the 25 competitors listed here.

Q. Okay. And you don't know what information a pharmacist is then provided on OxyContin if, in fact, they do push the glimmer button? You don't know what happens, right?

A. No. That detail was not provided here.

Q. And you have no evidence that a pharmacist in West Virginia, Huntington, Cabell, ever pushed that glimmer button, correct?

A. I have no evidence of that.

Q. And you don't know if a West Virginia pharmacist instead ignored the glimmer button and chose to proceed with the original purchase decision that they had made?

A. I don't have evidence of that. I think that was the question.

Q. Correct. And so, this is a brand selection document. If we go back to those couple of buckets that we were talking about earlier, this is in the brand selection. Pick my product over a competitor's, correct?

A. This would fall in that category.

Q. But there's still only one sale; it's just a question of which brand?

A. According to the glimmer button, yes.

Q. Okay. Let's turn to P-43300. That is the document that, at the top, says Managed Care Recap. Oh, you have it already. Thank you.

And so you testified that -- well, first of all, let me back up. This is a document that references Bergen Brunswig, correct?

A. Yes.

Q. And so, you are aware that this document pre-dates 2001 when AmerisourceBergen -- I'm sorry -- when AmerisourceBergen and Bergen Brunswig merged, correct?

A. Yes.

Q. So, there's no date on the document, but we know it's 2001 or earlier, right?

A. Yes.

Q. And this relates to direct mail services going to certain pharmacy customers, correct?

A. Yes.

Q. You cannot tell me how many pharmacies in West Virginia, Huntington, Cabell actually received any of these mailers, correct?

A. Correct.

Q. And is that because at the bottom of the document it says attached, please find a list of the good neighbor pharmacies to be included in this mailing, right?

A. Yes.

Q. And we don't actually have that document, do we?

A. I didn't have access to that document.

Q. And so, that document, according to this one-page summary, would be a list of the 1,800 pharmacies that were participating at a national level in this, correct?

A. Yes, a national level.

Q. And so, if you had that document you would be able to review, in fact, whether any of these are in Cabell-Huntington, correct?

A. Yes. That would be nice to have.

Q. And we don't have that because that wasn't produced by Purdue when it produced this document, right?

A. Correct.

Q. So, you don't know even -- let's say these were mailed to a pharmacy in Huntington-Cabell, which you don't know, right?

A. Yes.

Q. She just needs a verbal answer.

You don't know whether anyone actually read any of these mailers, right?

A. I don't know that anyone read the mailers.

Q. And you have no -- no information that anyone took any action in response to these mailers?

A. Right. I'm getting a little concerned here that --

that marketers know that these things create awareness. And so, you're asking me to say do I know that people read them. Well, typically what we do is we have a funnel and we know that there is a certain percentage of people who do read and open them.

Q. Dr. Mohr, that is not my question.

MS. MCCLURE: And, Your Honor, I would move to strike the testimony that is speculation regarding that. My question is --

MR. ACKERMAN: And, Your Honor -- I would ask that the witness be allowed to finish her answer.

MS. MCCLURE: Your Honor, my question was about whether the -- anyone receiving them would have taken action.

THE COURT: The answer was non-responsive, so I'll ignore the answer, but you can re-ask the question, Ms. McClure.

BY MS. MCCLURE:

Q. You have no information that anyone ever took action based on these mailers, correct?

A. Correct.

Q. Thank you. And, in fact, you don't know what the content was of those six mailers that are listed in that?

A. No.

Q. And you have no information to suggest that Bergen

Brunswig created any of the content in those mailers you haven't seen and don't know to whom they were distributed, correct?

A. Right.

Q. Okay. Let's look at Tab P-087 -- no -- P-08272, which is that four-page Purdue document from 1997. Let me know when you have that.

A. I have it.

Q. So, this is a 1997 internal Purdue memo, right?

A. Yes.

Q. And that summarizes Purdue's internal views on its relationship with four distributors?

A. Yes.

Q. And this is all about targeting pharmacy customers, correct?

A. Yes.

Q. And, again, if we go back to your report and the part of your report that I was focused on in the beginning, this is all about brand selection, correct, this bucket over here?

A. Correct.

Q. Okay. Let's look at P-26091, which is a longer document. Let me know when you have that document.

A. I have it.

Q. Okay. Again, this document generally is about brand

selection by pharmacies?

A. I wouldn't characterize it that way. It is offering services from AmerisourceBergen to the manufacturers.

Q. Those services being offered to the manufacturers would all then be to allow the manufacturers to target their own brands?

A. To market their own brands.

Q. Thank you. Okay. Let's talk about Tab -- Document P-43234. That is a Mallinckrodt produced document. Let me know when you have that.

A. I have it.

Q. Okay. You're very good at managing documents up there. So, thank you.

So, this is a document that is about Mallinckrodt encouraging AmerisourceBergen to switch secondary slots to primary physicians. Do you see that in number 2 there?

A. Yes.

Q. This -- you've talked about this being a document about fentanyl. This is not a document about fentanyl, though, is it? It's a larger program that includes AmerisourceBergen's purchases from all of Mallinckrodt's products.

A. I am not sure that I'm following you. It says at the bottom, I'll send you the ABC fentanyl volumes by month and, if you look on the back, those fentanyl sales volume by month are listed there.

Q. Right. But what I'm saying is that this is about how AmerisourceBergen could -- in order to achieve the next level of rebate, one of the ways that Mallinckrodt is pointing out it could do that is to change its fentanyl ordering, correct?

A. Yes.

Q. Okay. But you understand that this program overall, the VIP program, is not at all related to opioids? Instead, the suggestion from Mallinckrodt is just that you could change your fentanyl ordering in order to reach the next level of rebate, right?

A. Correct.

Q. This is a snapshot in time, right? We have no information to suggest or know whether AmerisourceBergen said, hey, Mallinckrodt, that's a good idea, not a good idea, took any action in response to this Mallinckrodt document at all, correct?

A. Correct.

Q. Let's look at P-43333. Let me know when you have that.

A. I do.

MS. MCCLURE: And, Your Honor, I just want to make clear for the purposes of my questioning here today that we, of course, maintain our objections to all of these documents and are questioning the witness simply in line --

THE COURT: I think the record is clear on that,

Ms. McClure. It should be.

MS. MCCLURE: Thank you.

BY MS. MCCLURE:

Q. So, this is about a drug called Fentora, right?

A. Yes.

Q. Do you know whether this Fentora segmentation analysis was ever actually completed by Xcenda?

A. I had a sequence of documents in my evidence or in my report that suggests they did.

Q. Do you -- but you have no information, even if the segmentation analysis was completed, to know whether Teva implemented anything as a result of this analysis, correct?

A. To be honest, I'd need to look at my report to answer that accurately.

Q. Okay. So, without looking at your report, you cannot tell me whether Teva implemented any part of this segmentation analysis?

A. The reason that I'm hesitating is there were so many documents about this Fentora target plan between the two companies that I don't want to misspeak and say that it wasn't done. This is part of an ongoing strategic partnership and it could be that I have the evidence that it was.

Q. Okay. But sitting here today, you don't know without looking at your report?

A. Without looking at my report given the hundreds of documents that I reviewed.

Q. Okay. So, we will come back to that. If it was implemented, which you don't know sitting here today, you don't know whether this would have increased prescription opioid prescribing or did increase prescription opioid prescribing, correct?

A. Did you ask if I have evidence that it increased it?

Q. Correct. Correct.

A. Yeah. If the question is did I have evidence that it increased, the correct answer is, no, I have no evidence.

Q. Okay. Let's look at P-43335. Now, this is a document called Payer Value Proposition Updated Recommendations and Timelines, correct?

A. Correct.

Q. And so, it's a recommendation?

A. This is a recommendation.

Q. You don't know if anything happened with this recommendation?

A. No, I don't.

Q. And so, you don't know if anything was implemented by Teva in response to this recommendation?

A. No, I don't.

Q. And so -- okay. You talked briefly about continuing medical education conferences. You don't believe that

distributors controlled any of the information that would have been told to doctors at a continuing medical education conference, right?

A. I have evidence in my report that the distributors were used to keep that information off the manufacturers' books.

Q. What are you talking about?

A. If you'd like me to point you to the page in the report that cites the document that says that.

Q. What I'd like you to do is tell me what you mean. You have information that suggests that distributors controlled the content that went to doctors at continuing medical education conferences?

A. Yes.

Q. Okay. Can you tell me what that is?

A. Yes. I have to refresh my memory.

Q. I'm asking you, Dr. Mohr, to tell me sitting here today testifying in this case whether you can recite that information or not?

A. I have evidence that the distributors hired the speakers to speak at continuing medical conferences to keep that information off the manufacturer' books.

Q. That's not my question, Dr. Mohr. My question is a different question. My question is do you believe that the information that the speakers spoke at a continuing medical education conference was information that was -- you don't

believe that that was information that the distributors told a speaker to speak, correct?

A. Again --

Q. I'm asking a very specific question and I would appreciate an answer to my very specific question.

A. I don't -- I can't say no to that.

Q. You can't say no to what?

A. Your question.

Q. Meaning you think that you do have evidence that speakers at continuing medical education conferences were told what to say by a distributor?

A. Yes.

Q. We'll come back to that. You understand patient adherence, that is something where a prescription has already been written by the time that the concept of patient adherence comes in, correct?

A. Yes.

Q. And so, patient adherence services can only come into play after a patient has a prescription in hand from a licensed doctor, right?

A. Yes.

Q. Okay.

MS. MCCLURE: Your Honor, may I have a moment?

THE COURT: Yes.

MS. MCCLURE: Thank you.

(Pause)

BY MS. MCCLURE:

Q. Dr. Mohr, back to the continuing medical education. I think what you're saying -- tell me if this is right. I think what you're saying is that you believe that there was a distributor who assisted in lining up a speaker for a continuing medical education because then the distributor would have the charge for that continuing education on its books; is that what you're saying?

A. Yes.

Q. Do you have any information to suggest that any information given out at a continuing medical education seminar was false or misleading in this respect?

A. No. No.

MS. MCCLURE: One moment.

(Pause)

MS. MCCLURE: Thank you, Dr. Mohr, for your time today. I have no further questions, but I do expect that my colleagues will.

THE WITNESS: Thank you.

THE COURT: Thank you, Ms. McClure.

Mr. Hester, are you next?

MR. HESTER: Yes, I am, Your Honor. Batting in the second spot today.

THE COURT: Okay.

CROSS EXAMINATION

MR. HESTER:

Q. Good morning, Dr. Mohr.

A. Hello, Mr. Hester.

Q. Dr. Mohr, let me begin by going through the points that you covered in your direct examination. I believe I kept track. I believe you went through 15 marketing propositions and let me just see if I've got them right. Situational analysis, market research, value proposition design, marketing plans, fee for services, savings cards, product launches, sales promotion offers, educational mailings, patient adherence programs, sales force training, thought leadership, articles in medical journals, coordination with key opinion leaders and public relations. I think that's the list of 15 you described.

A. That's pretty good. You left out segmentation.

Q. Okay. And market segmentation?

A. Yes.

Q. And am I right that there's nothing improper about any of those marketing activities?

A. No.

Q. And am I also right that those kinds of marketing activities are engaged in broadly across many industries in this economy?

A. Yes.

Q. So, there's nothing unusual about those marketing activities vis-a-vis prescription opioids, correct?

A. Correct.

Q. And am I also right that all of those marketing activities that you've described, that you identified from the documents you had reviewed, those were all available across a wide range of products that the distributors distribute, correct?

A. If you're asking if I reviewed documents for other types of products -- is that the question?

Q. No. My question was a little different. Is it your understanding that all of these activities that you've described were provided by distributors without reference to the nature of the product covered by those activities?

A. So, my understanding is that the distributors would use these services across a wide range of products.

Q. And that's because the distributors, in fact, sell a very wide range of products to pharmacies, correct?

A. Correct.

Q. And the distributors don't focus simply on selling one individual product, do they?

A. No.

Q. Their business model is to sell an entire portfolio and to have as wide a range of a portfolio with a pharmacy as they possibly can, correct?

A. Correct.

Q. And that's different from a manufacturer that may have one or two products that it's particularly focused on selling, correct?

A. Some companies have one or two products.

Q. Well, and you are aware that any one of a number of drug manufacturers would have a narrower product line that they're selling than the distributors, correct?

A. Right.

Q. Do you know the percentage of the distributors' product line that is made up of opioids as compared to non-opioid products?

A. No, I do not.

Q. And you understand that the distributors' product line, the product line they sell to their pharmacy customers, it covers tens of thousands of products?

A. Correct.

Q. And so, you understand that the products that distributors sell to their pharmacy customers are much wider than just opioids, correct?

A. I do understand that.

Q. And do you agree that because manufacturers are focused on selling individual products the nature of their promotional activity is going to differ from the nature of the promotional activity by distributors?

A. Yes.

Q. And do you understand, as well, that pharmaceutical manufacturers are responsible for securing FDA approval for a drug?

A. Yes, I do.

Q. And you understand that the manufacturer is obligated as a part of that process to submit data from clinical trials?

A. I do.

Q. And you're not aware of any evidence that a distributor conducted clinical trials to secure the approval of a prescription opioid, are you?

A. No. I did not testify to that.

Q. And you understand that based on these clinical trials that manufacturers run that they develop the content about what the addiction risks are and the benefits or the efficacy are for a particular prescription opioid, correct?

A. Yes, I do.

Q. And that information about the risks of a particular prescription opioid and the efficacy of a particular prescription opioid comes from the manufacturer, correct?

A. Correct.

Q. And that information about the risks of a particular prescription opioid and the efficacy of the opioid is also reflected on the label that's approved by the FDA, correct?

A. Yes.

Q. And in terms of developing that label, the label that is ultimately approved by the FDA, the manufacturer is responsible for making representations to the FDA about the risks and the benefits of a particular opioid, correct?

A. Yes.

Q. And the FDA ultimately has to approve the label information that's submitted by the manufacturer based on the information the manufacturer has provided about the risks and the efficacy of a particular prescription opioid, correct?

A. Yes.

Q. And the label that the FDA approves for a particular prescription opioid includes the uses, the efficacy, the risk profile and the benefits of the medication, correct?

A. Yes.

Q. And so, whatever the FDA approves for a particular label, for a particular prescription opioid, that's all supposed -- that's all that a manufacturer is permitted to convey to the public about the risks and the efficacy of that product, correct?

A. Correct.

Q. And distributors do not develop the labeling statements about the risks and the efficacy of a particular prescription opioid, correct?

A. Correct.

Q. So, when distributors provide a program to communicate advertising to pharmacies about particular prescription opioids, the content for that advertising comes from the manufacturer, correct?

A. With the exception of the value proposition designs that I've talked about previously. That value proposition design was done in consultation with the distributors.

Q. I was asking you about advertising.

A. Okay.

Q. And when -- when distributors communicate advertising to pharmacies about particular prescription opioids the content for that advertising comes from the manufacturer, correct?

A. Yes.

Q. And so, distributors are providing the communication form and the manufacturers are providing the messaging or the content, correct?

A. Yes.

Q. And so, that would be much like if an advertisement appeared on a website, the website is providing the channel for the communication, but the substance or the consent of the communication is coming from whoever purchased the advertisement, correct?

A. Correct.

Q. And you understand that not all manufacturer advertising or promotional activity is intended to expand the market for a particular product, correct?

A. Is this getting to the brand versus direct versus indirect?

Q. Yes. Some advertising activity is meant to build awareness, not necessarily to have a specific linear impact on sales, correct?

A. Yes. I think that's an oversimplification, but I can agree with that.

Q. But some marketing is intended to provide awareness or information about a product, correct?

A. Yes.

Q. And some marketing is intended to inform product selection within a product type, correct?

A. Yes.

Q. So, you might have, for instance, different prescription opioids that might be available for purchase or might be available for a particular prescription and the question is which choice is made between those individual prescription opioids, correct?

A. Yes.

Q. And that would be one form of marketing activity that a manufacturer might focus on trying to expand its sale after a prescription is written, correct?

A. I think so. I'm not sure that I'm following the sequence. It's just not the way it makes sense to me, so --

Q. Well, sometimes things may make sense to me.

A. Oh, yeah. Yeah.

Q. I'll try to keep on the same page with you.

A. Yeah. Yeah. Yeah.

Q. And you're aware, for instance, in the pharmaceutical industry that there may be alternative generic versions of a particular drug, correct?

A. Yes.

Q. And that the generic manufacturers may compete among each other for a share of the sales of those prescriptions for a particular drug, correct?

A. Yes.

Q. And so, for instance, a doctor might write a prescription for a particular drug, a particular prescription opioid, and the question then becomes competition among the generics to supply that particular prescription, correct?

A. Correct.

Q. And that's one form of marketing activity focusing not on expanding the overall sales of the category but rather on choice between the individual manufacturer within the category, correct?

A. Yes. That -- that is true.

Q. And you're aware that there's, in fact, a significant amount of competition among generic pharmaceutical manufacturers when they make an identical product?

A. Yes.

Q. And so, for instance, for some opioids there may be as many as five, or six, or seven different generics that are manufacturing that particular opioid?

A. Yes.

Q. And so, a part of the marketing activity may be not to expand the overall sales in the aggregate but rather to effect choice between which generic gets the sale, correct?

A. Yes.

Q. So, in that circumstance, the return on investment for a particular manufacturer's marketing program might well be vis-a-vis other competitors for that same prescription, correct?

A. Yes.

Q. You also agree that one of the ways marketing can be effective is to build relationships; in other words, build relationships between a distributor and a pharmacy by providing value added services?

A. Correct.

Q. And that can also be true as between a manufacturer and a distributor, that the distributor wants to build a stronger relationship with the manufacturer, correct?

A. Correct.

Q. And that's a -- that's a legitimate form of marketing that isn't necessarily focused on overall sales growth but rather on relationship expansion, correct?

A. Yes. I just feel compelled to say that, as I stated yesterday, we start with awareness. We go to influence. And we go to sales. So, all of these ultimately are trying to culminate in the sales.

Q. But many, many forms of marketing are more around relationship building than they are delivering some specific value in terms of expanded demand, correct?

A. I don't agree with that. Relationship marketing, the purpose is ultimately to grow sales.

Q. Well, but for instance, for a distributor, a distributor is competing for the share of pharmacy sales, correct?

A. Yes.

Q. And so, a distributor wants to build a strong relationship with the pharmacy by providing value added services vis-a-vis the pharmacy, correct?

A. To get a bigger percentage of the sales.

Q. A bigger percentage of the sales of that pharmacy, right?

A. Correct.

Q. You're familiar with the concept of physician

detailing, correct?

A. Yes.

Q. And you understand that physician detailing relates to conveying the benefits and the product attributes about a particular drug to a doctor?

A. Yes.

Q. And you're not aware of any distributors that engaged in physician detailing, correct?

A. Yes. We went through this just previously.

Q. So, you're not aware of distributors engaging in physician detailing?

A. Physicians -- distributors did not detail physicians.

Q. And when you say physicians did not detail -- I'm sorry. I'll back up. When you say distributors did not detail physicians, you mean the distributors did not have sales forces that were dedicated to calling on physicians, correct?

A. That's what I mean.

Q. And man -- in contrast -- sorry. In contrast, manufacturers do call directly on physicians to describe the risks and the benefits of particular drugs, correct?

A. Correct.

Q. And, in fact, manufacturers maintain large sales detailing forces that have as their role calling consistently on doctors about particular products, correct?

A. Correct.

Q. And, in fact, manufacturers invest a substantial amount of money in those sales forces that call on doctors, correct?

A. Correct.

Q. And is it your understanding that when manufacturers have those sales details that are charged with calling on doctors the purpose is to expand the sales of their products?

A. Yes.

Q. And as part of their sales efforts and calling on doctors, you understand that manufacturers through their sales force make representations to the doctors about the risks and the benefits of the medications they're discussing, correct?

A. Yes.

Q. And, in particular, in relation to prescription opioids, manufacturers have large sales details that called on doctors and made representations about the risks and the benefits of particular prescription opioids, correct?

A. Yes.

Q. Now, I think we've gone through this before, so I won't spend too much time on it. You are not offering the opinion that any advertising communication of any sort or any marketing activity by any of the distributors was false or

misleading?

A. I am not offering an opinion on that.

Q. And you're not offering the opinion that any of the advertising or any of the marketing activity by any of the distributors in this case was in any way unlawful?

A. Correct.

Q. And you're not offering the opinion that any of the marketing activities by any of the distributors was improper, correct?

A. Correct.

Q. Let me now turn to a few of the specific documents. Dr. Mohr, you're pretty good with these documents. Plaintiffs' 42701, which is one of the ones that you looked at before.

And let me ask you, Dr. Mohr, if you could look at Page 22 of this. And I'm sorry, Dr. Mohr. I'm looking at -- yes, Page 22. And I'm using the numbers at the bottom right. There's a lot of numbers on these documents that have crept in over time, but I'm using the numbers on the bottom right, okay?

A. Thank you.

Q. And this is a page that you talked about where you said McKesson manufacturer marketing touches key points in the healthcare continuum. Do you see that page?

A. Yes. Uh-huh.

Q. You don't know whether this program was actually implemented, do you?

A. I do have evidence that McKesson did engage in the key point in the healthcare continuum talking to patients. So, I do have that.

Q. No. I'm asking you about something very specific. This is a specific proposal about McKesson manufacturer marketing, correct?

A. Yes.

Q. You don't have evidence, do you, that this program was implemented?

A. When you say "this program", are you -- this is a PowerPoint that pitches all their marketing services. So --

Q. Well, maybe since we're both just looking at a document and reading it together, let me start off with the page before, 21. Other marketing services are also available --

A. Right.

Q. -- via McKesson manufacturing and marketing, right? Do you see that?

A. I do.

Q. And do you understand this was a proposal or a pitch?

A. A pitch deck.

Q. And so, you don't know whether it was actually accepted and implemented, correct?

A. Not this particular pitch deck.

Q. Right. And so, if you look over on Page 23 where it says manufacturers can use MMM as a single point across multiple business disciplines; do you see that?

A. I do.

Q. And so, what I wanted to ask you about is you're not aware of any manufacturer that actually implemented MMM, this particular program?

A. In my experience, companies don't market marketing services with no intention to execute and deliver them.

MR. HESTER: Your Honor, I move to strike as speculative and not responsive.

MR. ACKERMAN: I would oppose that, Your Honor.

THE COURT: Pardon me?

MR. ACKERMAN: I would oppose that.

THE COURT: Well, I'll overrule the motion to strike and give it such weight as it deserves. And you may proceed, Mr. Hester.

MR. HESTER: Okay. Got it.

BY MR. HESTER:

Q. Dr. Mohr, you don't know whether this particular program -- I'm not asking about your general experience. I'm asking about this particular program, MMM. You don't know if this was implemented?

A. Not this pitch deck.

Q. And I take it you didn't identify anything in this deck

that you consider to be improper?

A. No.

Q. And, in fact, many of the marketing activities that you've described today in your testimony and yesterday, these are very conventional across -- across the economy, correct?

A. Yes. I just feel like I'm -- I'm struck again by the juxtaposition that these are very conventional marketing strategies and the prior set of questioning was this is a very unique industry. So, you can't have conventional marketing strategies used for controlled substances and have both things happening at the same time.

Q. Well --

A. It's -- it's paradoxical.

Q. Well, the paradox is you can have specialized industries, but very conventional marketing activities, correct?

A. You could.

Q. And that's, in fact, what you've seen in your study across different industries? There may be particular attributes of different industries, but the marketing activities share a common shape, correct?

A. Correct.

Q. Let me ask you to turn to P-42508. This is the document headed Nucynta and Nucynta ER program review. Do

you see that?
A. Yes, I do.
Q. Let me ask you to look -- well, first, let me ask you a general question. You discussed a market update that's provided in this document, correct?
A. Yes.
Q. And there's nothing wrong with a distributor providing a -- an update on market trends to a manufacturer, is there?
A. There's nothing wrong with that.
Q. It's quite conventional, right?
A. It's part of the situation analysis.
Q. And if you could look at Page 11 of the document, this is where you previewed a co-pay card program. Do you see that?
A. Yes.
Q. You don't know whether this program was actually implemented, do you?
A. The data in this slide deck suggests that it was.
Q. So, you're just reading the slide deck and assuming it was?
A. No. It actually shows the results from the campaign on Page 14.
Q. But you're just reading the document? That's the basis of your knowledge? You're just looking at the document and assuming it was implemented?

A. I don't think that McKesson made up the numbers on Page 14.

Q. You talked about the sampling program. Sampling, I take it, is a common tool in marketing?

A. Yes, it is.

Q. Across many industries?

A. Yes.

THE COURT: How much more do you expect to have, Mr. Hester?

MR. HESTER: Well, I've been chastened by Your Honor not to underestimate here. I won't be -- it won't be two minutes, I'll say that.

THE COURT: How many?

MR. HESTER: It won't be two minutes. And probably more like ten.

THE COURT: Okay. And you can restore your credibility with me, Mr. Hester, but --

MR. HESTER: If I hit ten, Your Honor?

THE COURT: Ms. Wicht, are you going to cross examine or somebody from your side?

MS. WICHT: Yes, Your Honor, although I can assure the Court and the witness that nobody's schedule will be jeopardized by what I'm intending to do for the afternoon.

THE COURT: Well, Dr. Mohr has to make a 4:30 flight.

THE WITNESS: I need to leave at 4:30 for a 5:30 -- 5:50 flight.

THE COURT: Oh, okay. Well, that's better. That's a lot better.

THE WITNESS: Thank you, everyone.

THE COURT: I don't have anything over the noon break today for a change, so I'm going to suggest we -- can we come back at 1:00 and then we'll maybe -- maybe knock off around 4:00 and that way we can be pretty sure we'll get through with Dr. Mohr? Is that all right?

MR. HESTER: That's fine by me, Your Honor.

THE COURT: Is that okay?

MS. MCCLURE: Yes, Your Honor.

THE COURT: Okay. Let's come back at 1:00 and you can step down and we'll see you back at 1:00, Dr. Mohr.

THE WITNESS: Thank you.

(Recess taken)

THE COURT: All right. Mr. Hester.

MR. HESTER: Thank you, Your Honor.

BY MR. HESTER:

Q. Dr. Mohr, before the lunch break, you had talked about continuing medical education programs. Do you recall that testimony?

A. Yes, I do.

Q. And are you aware that a number of the continuing

medical education programs, or CME programs, arranged for by distributors were for their pharmacists?

A. Yes. Some of them were.

Q. And are you aware that for some of those CME presentations the content was not prepared by distributors for those CME presentations, but it was prepared for by manufacturers or others?

A. Yes.

Q. We talked about the co-pay cards or assistance cards. Do you recall that in your testimony this morning?

A. Yes.

Q. And am I right that the co-pay cards apply after a patient has a prescription? In other words, a doctor has decided there's legitimate medical need and then the co-pay assistance is available for somebody who may need help with their insurance premium?

A. Yes.

Q. So, it doesn't -- it doesn't apply until after the prescription has been written, correct?

A. Correct.

Q. And there's no illegitimate purpose in providing a co-pay card, is there?

A. No.

Q. And adherence programs, same sort of thought, adherence programs that encourage people to take their medicine as

prescribed, there's nothing wrong with that, is there?

A. No.

Q. Let me ask you to look back at Exhibit 42508, please, Slide 32.

A. Yes.

Q. And this is a slide I believe you discussed earlier today where there's a heading, New Ten Free Pills Program. Do you see that?

A. Yes.

Q. And I take it this was not, in fact, a giveaway of ten pills, was it? It was a promotional card that had the effect of paying for ten pills if a patient had a prescription?

A. That is correct.

Q. So, again, this applied after a patient had a prescription and an assistance card might be available to, in effect, pay for ten pills?

A. Yes.

Q. Let me ask you to look at Exhibit 8272, please, and this is a memo written -- it's an internal memo from Purdue, right?

A. I haven't found it yet.

Q. Oh, sorry.

A. That's okay.

Q. 8272. It's the one that's headed National Accounts

Memorandum.

A. Oh, that one? Okay. Let me grab that one. Thank you for telling me which one it was because I don't know the numbers by memory, but I know what the other things are. Yes, the National Accounts Memo.

Q. So, this is an internal memo written by Purdue, correct?

A. Yes, correct.

Q. And you don't know what Purdue ended up deciding after it wrote this memo, do you?

A. Could you re-state the question? I'm sorry. I just didn't hear it.

Q. You don't -- you don't know what Purdue ended up deciding to do after it wrote this memo, do you?

A. No, I do not.

Q. And let me ask you to look at the second page of the document, please. There's a -- Under Obstacles to Our Growth, the heading there; do you see that?

A. Yes, I do.

Q. And the first sentence reads obstacles to our growth lie predominantly with our reluctance to spend money on wholesaler programs; do you see that?

A. Yes.

Q. And were you aware that Purdue had a reluctance to spend money on wholesaler programs?

A. According to this memo, that's what I read.
Q. Yes. Let me ask you to look at Exhibit 42911, please. This is the focus group memo.
A. Yes. Let me grab that.
Q. And this memo is more than 20 years old, correct?
A. It was in October, 2000.
Q. And so, do you know whether there are further memos that were also reflecting this kind of focus group research or is this the last one you saw?
A. No. There were approximately three documents that I reviewed that were market research. This one was qualitative. Others were quantitative.
Q. And when you say qualitative, that means based on interviews of participants?
A. Qualitative means that you cannot analyze it statistically, that it's usually verbal insights that are given.
Q. So, from among the thousands of documents you reviewed, you saw three dealing with focus groups or research?
A. Yes, that I recall.
Q. And this involved interviews of 15 doctors; is that right?
A. In this particular study.
Q. You don't know whether any of the recommendations in this document were acted upon, do you?

A. Let me just recall the recommendations. I can't draw a linear cause and effect relationship between this and other documents, but given that I saw the other documents that did offer the key opinion leaders and the continuing education on pain management, there is correlation between those two.

Q. But you'd just have to guess as to whether these recommendations led to those later acts, right?

A. Yes, that's correlated.

Q. But what you mean by "correlated" is one followed after the other, correct?

A. I can't assert causation. I can't assert that this caused the continuing education seminars on pain management.

Q. Yes. Do you see that in the -- under the conclusions and recommendations, under Point 5, there's a third sentence that has a recommendation, educate physicians about treatment strategies that reduce the risk of narcotic addiction? Do you see that?

A. Yes, I do.

Q. And were you aware that that was one of the recommendations in this document, to reduce the risk of narcotic addiction by educating doctors?

A. Yes. I did read this recommendation previously. The family physicians were worried about creating addicts and the final recommendation was the sponsoring of the pain management conferences and lectures by opinion leaders to,

as you're saying, educate them about the attention -- excuse me -- addiction and tolerance issues.

Q. And so, part of the recommendation here is educate doctors on risks of addiction, correct?

A. That is correct.

Q. And there's nothing in these recommendations in this focus group that you view as improper in any way, is there?

A. I -- I would cautiously agree with that statement.

Q. And there's certainly no statement in these recommendations that Purdue engaged in any misleading or false activity?

A. The only reason that I'm hesitating is that number 9 statement that says focusing on these issues and OxyContin marketing material make position that is a safer narcotic alternative. That just kind of skates a line.

Q. Well, but that doesn't recommend that there would be any false or misleading statements, correct?

A. Correct.

MR. HESTER: That's all I have, Dr. Mohr. Your Honor, I did it.

THE COURT: You did it. You're -- you're back at the top of my good graces list.

MR. HESTER: Thank you, Your Honor.

MR. FARRELL: Objection, Your Honor.

MR. HESTER: Thank you, Your Honor.

THE WITNESS: Thank you.

THE COURT: You're number two now, Mr. Farrell.

(Laughter)

MS. WICHT: It will take just a moment.

THE COURT: You're on the list, too, Ms. Wicht.

MS. WICHT: I'm sorry?

THE COURT: You're on the good graces list, too.

MS. WICHT: Oh, well, thank you very much, Your Honor. Now I feel a lot of pressure to maintain that during this examination, but I appreciate the Court's comment.

MR. ACKERMAN: Can we get that list in discovery, Your Honor?

MS. WICHT: I have some legal advice for you about that, Your Honor.

CROSS EXAMINATION

BY MS. WICHT:

Q. Good afternoon, Dr. Mohr.

A. Hello.

Q. My name is Jennifer Wicht and I represent Cardinal Health. You and I have haven't met before, so it's -- I will say it's nice to meet you --

A. Thank you.

Q. Although somewhat in this setting. I am going third in the line-up here, obviously, and I don't have very many questions and I'm going to just try to be very targeted

because I'm trying not to repeat anything that anyone did before.

A. Thank you.

Q. Okay. So, my first question, Dr. Mohr, is that prior to being retained as an expert in this opioid litigation you had never heard of Cardinal Health before, correct?

A. I frequently scan for case studies to use in my classes and Harvard Business Review has a section for educators and, in this particular case, there is a case study that educators use and it is on one of the distributors. And because it was about five years ago, I can't recall which one it was. So, it could have been Cardinal Health, but it could have been McKesson.

Q. So, outside of whatever that potential Harvard business publication was, outside of that, if that was about Cardinal Health, you'd never heard of Cardinal Health before, correct?

A. Correct.

Q. I'm going to ask you about -- I'm going to sort of jump into some specifics now and I'm going to ask you about patient adherence services.

A. Yes.

Q. And with respect to Cardinal Health in particular. You do not know if Cardinal Health has provided patient adherence -- patient adherence services for opioid

medications, correct?

A. Correct.

Q. I'm going to jump to field sales support and, Dr. Mohr, you have not offered any opinion in your testimony here today or in your report that Cardinal Health provided field sales support to manufacturers, correct?

A. Correct.

Q. Turning to -- back to continuing medical education. Am I correct that you don't know whether any prescriber or pharmacist from Cabell County or the City of Huntington attended any continuing medical education that Cardinal Health was also involved with, correct?

A. Correct.

Q. And that would be true for any of the distributors here, as well, correct?

A. Correct.

Q. And you are not offering any opinion about the effectiveness of any continuing medical education program in which any distributor here was involved, correct?

A. Correct.

Q. And you're not offering any opinion on whether any such continuing medical education that a distributor here was involved with affected demand for opioid medications in any way, correct?

A. Correct.

Q. I'm going to turn to the subject of return on investment on market.

A. Yes.

Q. You have not tried to measure how marketing services by Cardinal Health generated return on investment for any opioid manufacturer, correct?

A. Correct.

Q. Or even if it did generate such a return on investment, correct?

A. Correct.

Q. And you don't have any evidence that Cardinal Health's compensation was tied to increased opioid sales, correct?

A. Scanning my brain for the thousands of pages right now, so just give me a moment.

Q. No problem.

A. I feel comfortable saying correct to that.

Q. Thank you, Dr. Mohr. Okay. I'm going to ask you some questions that relate to a document that you looked at with Mr. Ackerman, which is P-43195. It's the Cardinal brochure. You're certainly welcome to have it in front of you. I'm not going to ask you questions that stem from the document, but that's what I'm working from, so I invite you to look at it.

A. Yes, thank you.

Q. When you testified earlier with Mr. Ackerman you

mentioned a program that's referenced in that document called First Script, correct?

A. Yes. Yes.

Q. Now, you didn't offer any opinions about First Script in your report in this case, correct?

A. My understanding of First Script is that it was a bundled service that included auto ship, service flash and first facts. And so, I did offer opinions about auto ship, service flash and first facts. I did not call them First Script because they were typically broken down because each of those was a different fee for service and resulted in different reach to the pharmacists.

Q. But when you discussed auto ship in your report, Dr. Mohr, isn't it correct that you did not list the Cardinal Health auto ship program there?

A. That is correct.

Q. And you did not cite in your report a single example of a First Script shipment going to any pharmacy in Cabell-Huntington, correct?

A. Correct.

Q. And turning now to service flash, you didn't --

A. Yes.

Q. I'm sorry. You did not cite in your report or your testimony today a single example of a service flash message going to any pharmacy in Cabell County or City of

Huntington, correct?

A. Correct.

Q. And the next one on that list in the brochure that you talked about this morning is called First Facts. And you didn't offer any opinions about First Facts in your expert report in this case, correct?

A. Are you asking in general or are you asking with respect to Cabell County and Huntington?

Q. I'm asking in general with respect to Cardinal Health?

A. Correct.

Q. Okay.

MR. WICHT: May I take a moment, Your Honor?

THE COURT: Yes.

(Pause)

MR. WICHT: That's all I have. And I think I succeeded in maintaining my position, if I may be so bold.

Thank you very much, Dr. Mohr.

THE COURT: I'm sorry.

Mr. Ackerman?

MR. ACKERMAN: Give me one moment, Your Honor, but I think I may jump ahead of Mr. Hester on your list.

(Pause)

MR. ACKERMAN: I'm only walking up here to say that I have no questions.

And thank you, Dr. Mohr, for your time.

THE WITNESS: Thank you.
THE COURT: May Dr. Mohr be excused?
MS. MCCLURE: Yes, Your Honor.
MR. HESTER: Yes, Your Honor. Thank you.
MS. WICHT: Yes.
MR. ACKERMAN: Yes.
THE COURT: Dr. Mohr, we made it with many hours to spare. So, you're free to go and we thank you for coming all the way from Montana to help us out here and you're excused.
THE WITNESS: Thank you very much.
MR. ACKERMAN: Yeah. Leave the documents there.
THE WITNESS: I can leave them here?
MR. ACKERMAN: Yes.
THE WITNESS: Okay.
MR. ACKERMAN: We just need a minute, Your Honor, to shuffle the decks.
THE COURT: Okay.
MR. FARRELL: Are we ready?
Your Honor, the plaintiffs have the privilege of calling Dr. Katherine Keyes, K-e-y-e-s.
THE COURT: Okay.
COURTROOM DEPUTY CLERK: Would you please state your name?
THE WITNESS: Katherine Keyes.

COURTROOM DEPUTY CLERK: Thank you. Please raise your right hand.

DR. KATHERINE KEYES, PLAINTIFF WITNESS, SWORN

COURTROOM DEPUTY CLERK: Thank you. Please take a seat.

THE COURT: Good afternoon, Dr. Keyes.

THE WITNESS: Good afternoon.

DIRECT EXAMINATION

MR. FARRELL:

Q. Will you please state your name for the record?

A. My name is Katherine Keyes.

Q. Dr. Keyes, what is your profession?

A. I'm an epidemiologist.

Q. And so, we had the pleasure of an epidemiologist yesterday by the name of Dr. Smith. Do you know Dr. Smith?

A. I'm sorry?

Q. Dr. Smith, do you know Dr. Smith?

A. I do.

Q. And just to give the Court some brief context, can we bring up Demo 235, Page 6? Do I need to push a button? Is it on my end?

I'll see if I can do it like this in the meantime. Does that work? Oh, there we go.

Dr. Keyes, do you recognize figure 9 from your report?

A. I do.

Q. And is this a data visualization of the data provided by Dr. Smith in this case?

A. Yes.

Q. And is it your understanding today you will be building upon that?

A. I will.

Q. Very good. So, we'll bypass some of the preliminaries that we went through with Dr. Smith, but I do want to start with your definition of epidemiology. Would you please give the Court the definition that you use?

A. Yeah. It is the science of studying causes and distributions of health outcomes in populations.

Q. And how do epidemiologists go about understanding causes and distributions of public health?

A. We collect data on the health and populations and we try to assess what risk factors are causing those health problems. So, it's both data collection, data analysis, and then synthesizing our results with the existing scientific literature to come to consensus on causation.

Q. What qualifications do you need to be an epidemiologist?

A. Typically, you need advanced training in the principles and methods of epidemiology through a graduate degree.

Q. And are there professional organizations?

A. Yes.

Q. And can you tell the judge which professional organizations exist?

A. The main one in North America is the Society for Epidemiological Research.

Q. And are there peer-review journals?

A. Yes.

Q. And can you name to the judge a couple of the peer-review journals that epidemiologists in your field consider to be authoritative?

A. There's the *American Journal of Epidemiology*. There's a journal called *Epidemiology*. There is the *International Journal of Epidemiology*. There's *Annals of Epidemiology*. And others.

Q. All right. Do epidemiologists in your field rely on these journals when performing their analyses?

A. Yes.

Q. And in addition to being -- having published peer-review journals on epidemiology, do epidemiologists also seek to get published in other journals in other fields of medicine?

A. Yes. Epidemiology is really a set of methods. And so, within epidemiology, you have people who focus on different substantive areas. And so, I'm a substance abuse epidemiologist. So, I publish in substance abuse journals and epidemiology journals.

Q. In addition to the academic world do epidemiologists work with and provide input for national health organizations?

A. Yes.

Q. Can you tell the judge briefly about the role of epidemiology in some of our national health organizations?

A. Yes. There's a lot of epidemiologists who work at the Centers for Disease Control and Prevention, the CDC, the NIH. A lot of those epidemiologists will work internally, you know, understanding health outcomes through their work in the governmental organizations. But then those organizations also fund externally epidemiologists like me.

Q. Now, I'm going to endear myself to the court reporter and remind you to slow down.

A. Okay.

Q. Especially when we get to some of the bigger words. You mentioned NIH. Can you tell the Court what is NIH and what, if any, is your relationship with NIH?

A. NIH is the National Institute of Health and there are a number of institutes within the NIH. And those institutes fund research extramurally. So, by that, it means outside of the NIH. So, they fund universities like mine to the researchers within them to conduct research. And I'm currently funded by the National Institute of Drug Abuse, National Institute of Alcohol Abuse and Alcoholism and The

National Institute of Mental Health.

Q. And are those all within the purview of the National Institute of Health?

A. They are.

Q. All right. We heard earlier from Dr. Smith that epidemiologists specialize. Do you have a specialty?

A. Yes.

Q. And what is your specialty?

A. Opioid use, Opioid Use Disorder, and related comorbidities.

Q. Dr. Keyes, what do you believe to be your role today in court?

A. I believe my role is to tell the Court about the report that I wrote that details the extent of Opioid Use Disorder and related harms in the Cabell-Huntington community and address factors that led to -- the causal factors that led to harms in the Cabell-Huntington community.

Q. And how did you first become involved in this litigation?

A. I got an e-mail from Mr. Farrell, who had read an article of mine in the American Journal of Public Health and had some questions about the article and wanted me to help interpret some county overdose data.

Q. Do you remember or recall which article that was?

A. It was an article in the American Journal of Public

Health about urban and rural differences in prescription opioid misuse and overdose.

Q. Dr. Keyes, have you ever testified in court at a trial before?

A. No.

Q. You have been in court, though, before?

A. Yes.

Q. Can you tell the judge about your previous experiences with being involved in civil litigation, especially in the opioid litigation?

A. Yes. I testified in a Frye hearing in New York.

Q. And do you know the results of that?

A. I -- I think I passed. I haven't heard any different.

Q. All right. So, you understand that today is a little bit different, that instead of just talking about your qualifications, we're going to get into detail on direct with your findings and then cross examination from the defendants. Have you been deposed before?

A. Yes.

Q. In this case?

A. Yes.

Q. How many times have you been deposed on your opinions related to opioid abuse?

A. I believe four or five. Four.

Q. Who else has disclosed you as an expert in the opioid

litigation? Not -- not consulted with you, but formally disclosed you as an expert?

A. I have -- I have been disclosed, I believe, in the various MDL tracks, the case Track 1, 2 and 3, as well as involved in the New York State litigation.

Q. And I understand they're picking a jury as we speak.

A. I'm -- I'm not familiar with their -- with what they're doing.

Q. All right. We're going to turn now to qualifications and, with the Court's indulgence, I am going to spend a little bit of time with this aspect. So, I would like for you to first start and tell the Court about your educational background.

A. Sure. I received a Masters degree in Epidemiology from Columbia University. I stayed at Columbia to do my doctoral training and I received my Ph.D. in 2010. I then did a postdoctoral fellowship at Columbia for several years. And then I started on faculty as a tenure track assistant professor in 2012.

Q. And have you -- I don't know the right wording for this. Are you a tenured professor at Columbia?

A. Yes. I received tenure and my title is Associate Professor of Epidemiology.

Q. So, these are academic positions at Columbia University and I've seen in the title the Mailman School of Public

Health. Can you describe for the judge what that is?

A. Yes. The Mailman School of Public Health is the public health school at Columbia University.

Q. And do you also hold teaching positions?

A. I do.

Q. What and where have you taught?

A. I teach graduate courses at Columbia in the School of Public Health and I have also taught at various universities. I teach at the University of Michigan in Ann Arbor. I've taught at the University of Cape Town in South Africa. And other various short courses at universities in other locations.

Q. Do you teach undergraduate classes?

A. No.

Q. What do you primarily -- or what students do you primarily teach?

A. I primarily teach Masters and doctoral-level graduate students.

Q. Do you know how many Masters students you've taught approximately?

A. Thousands.

Q. What about doctoral students? Have you -- how many doctoral students have you taught?

A. My primary role of doctoral students is mentoring them and I've mentored approximately 30 to 40 doctoral students.

Q. Have some of the doctoral students that you've mentored, have they gone on to academic placements at universities in America?

A. Yes.

Q. Can you tell the judge briefly a couple of the universities your doctoral students are now teaching at?

A. My doctoral students have gone throughout the world really. Most recently, UCLA, Harvard, University of Iowa and other places in the U. S.

Q. Now, publications, are you published, Dr. Keyes?

A. Yes.

Q. How many peer-reviewed articles have you had published?

A. I believe the last count was 306.

Q. And so, I don't know what this means. Well, I do because I asked you the other day, but 70 of those articles are first authored. Can you tell the judge what first authored means?

A. That means I took primary responsibility for the conception of the study, the data analysis and the writing of the manuscript.

Q. And will you tell the judge a couple of the journals that your articles have been published in?

A. Various publications. JAMA Psychiatry. All the epidemiology journals I mentioned earlier my work has been published in. Major medical journals. Pediatrics. The

British Medical Journal and other major substantive journals in my field.

Q. I'm afraid I'm not going to let you get off that easy. Have you been published in the American Journal of Psychiatry?

A. Yes.

Q. And the American Journal of Epidemiology?

A. Yes.

Q. Pediatrics?

A. Yes.

Q. JAMA Psychiatry?

A. Yes.

Q. And JAMA stands for?

A. Journal of the American Medical Association.

Q. And then, Lancet Psychiatry, what is Lancet Psychiatry?

A. That's another major international publication, journal publication.

Q. Now, I'm going to also have you explain what an h-index means to the Court.

A. An h-index is a measure of how many times your work is being cited by others. And so, it's a measure of sort of the influence you have as a scientist in the world.

Q. And what is your current h-index?

A. I believe it's about 75.

Q. I also understand that from the Web of Science in 2019

you were noted as a, quote-unquote, "highly cited researcher". Will you explain to the Court what that means?

A. That means that I'm in the top one percent of all scientists in terms of the people who are studying my work in the world.

Q. Now, you also are principal investigator in studies; is that correct?

A. Yes.

Q. And will you tell the judge about your role as a principal investigator with a particular project from the National Institute of Health?

A. I currently have three projects that I'm the principal investigator on that are funded by the National Institute of Health. One is tracking trends over time in adolescent substance use and seeing how those trends correspond to trends in adolescent mental health to try to understand the causative factors of why trends -- why the trends over time are occurring and their correlation with mental health problems.

Q. And so, what is the funding for that project?

A. That comes from the National Institute on Drug Abuse.

Q. And do you know how much it is?

A. I don't off the top of my head.

Q. Also, Columbia University in 2019, you're involved with PHIOS, P-H-I-O-S. Can you explain to the Court what that

is?

A. Yes. That is a center at Columbia that is focused on opioid policy and understanding how opioid policy and other factors related to the overdose epidemic are influencing the health populations.

Q. And that's the Policy and Health Initiatives on Opioids and Other Substances, correct?

A. That's right.

Q. And what is your role with this group?

A. I'm on their faculty.

Q. Now, you're also involved with SAETP. I don't know how to say that or if you're supposed to say it. SAEPT?

A. SAEPT.

Q. That's a Substance Abuse Epidemiology Training Program at Columbia University. Will you explain to the Court what that is?

A. We recruit and train doctoral students and postdoctoral fellows in substance abuse epidemiology, our methods, and get them involved in research in our -- in our field.

Q. And you're also involved with HEALing Community Studies and HEALing is capital H, capital E, capital A, Capital L, -ing. Will you tell the Court about your involvement with this study

A. Yes. It stands for Helping and Addiction Long-Term and it is a suite of studies that are funded by NIDA, National

Institute on Drug Abuse. And I'm involved with the Healing Community Study, HCS, which is a -- a large implementation science initiative where four states have received funding and universities in those states have received funding to work with communities.

We work with people with lived experience with drug addiction, treatment providers, law enforcement, everyone in the community who is a stakeholder in developing programs to reduce overdose.

We work with those communities to try to see what their needs are and see how we can design and implement overdose prevention initiatives that meet the needs of the community.

Q. And how much is that funding?

A. The HCS funding is upwards of $300 million, I believe.

Q. And that's from NIH?

A. Yes.

Q. And do you have sufficient funding for your project?

A. Absolutely not.

Q. What about your peer-reviewed articles that are related specifically to opioid use and related harms? How many times have you been published in that area?

A. I believe between 35 and 40.

Q. And is this a well-developed scientific area in epidemiology in your opinion?

A. Yes.

Q. And have you also written textbooks?

A. Yes.

Q. How many textbooks have you written?

A. Two.

Q. And who published them?

A. Oxford University Press.

Q. And what is the name of the first textbook?

A. *Epidemiology Matters: A New Introduction to Methodological Foundations*.

Q. And is it being used by universities currently?

A. It is.

Q. It is, in fact, being used at Columbia?

A. Yes.

Q. Tell the judge why you wrote that textbook.

A. I taught epidemiological methods to graduate students for years and, you know, the textbooks that we were using I felt didn't sufficiently present the material in a way that was the best way to engage students and help them learn the foundations of our methods. And so, I wrote a textbook based on my teaching experience.

Q. And have you kept track of which universities are using it?

A. I haven't kept specific track. I receive e-mails sometimes from people who ask questions and want additional material. And I also created a set of lecture sites for

every chapter. I created exercises for every chapter that students can use. So, faculty will reach out to me to get those materials.

Q. Okay. The second textbook, *Population Health Science*, can you tell the judge about the second textbook you wrote?

A. Yes. When I finished writing *Epidemiology Matters*, I realized that I had a lot more to say about the way we conduct health science research and that I really -- *Epidemiology Matters* was really focused on the nuts and bolts of how to design and interpret epidemiological evidence and I realized I wanted to say more about really the philosophical foundations of our field and how to really think about the health of populations. And so, I wrote a second book that's a much broader view of different conceptual frameworks that you can use to try to understand why communities get sick and how you study that.

Q. And do you serve as a journal reviewer?

A. I do.

Q. And which journals have you served in that capacity?

A. Many. Should I --

Q. Tell the judge a couple of the ones that have the heftier weight.

A. Sure. New England Journal of Medicine. All of the JAMA journals. Lancet. All of the major medical journals that we mentioned earlier. I also serve as a peer-reviewer

for those journals.

Q. Do you also serve on editorial boards for peer-review journals?

A. Yes.

Q. Which ones?

A. I am an Associate Editor of the journal Drug and Alcohol Dependence and I'm a Field Editor of the journal Alcoholism: Clinical and Experimental Research.

Q. And have you served as an invited lecturer in your professional career?

A. Yes.

Q. And can you tell the judge briefly about your invited lectures?

A. Yes. I have been invited to give lectures in many universities in the United States and throughout the world. All the major medical -- major schools of public health have invited me to present my work.

Q. What about your professional affiliations? Which of the professional organizations do you belong to?

A. I belong to the Society for Epidemiological Research. Also, the College on Problems of Drug Dependence and the Research Society on Alcoholism and other various professional societies that are related to either epidemiological methods or substance abuse research.

Q. And you recently are the recipient of an award, are you

not?

A. Yes.

Q. And will you tell the judge what you were awarded?

A. The Society for Epidemiological Research last year awarded me with the Mid-Career Award, which is the award for the most distinguished society member in the middle of their career.

MR. FARRELL: Judge Faber, at this time, we would ask the Court to recognize Dr. Keyes as an expert in the field of epidemiology specializing in opioid use, Opioid Use Disorder, and related harms.

THE COURT: Is there any objection?

MR. HESTER: No objection, Your Honor.

MS. HARDIN: No objection.

MR. NICHOLAS: No objection.

THE COURT: I find that Dr. Keyes is an expert in the field of epidemiology, specializing in opioid use, Opioid Use Disorder, and related harms.

That got it, didn't it, Mr. Farrell?

MR. FARRELL: Yes, Your Honor.

And now you can add this to your distinguished curriculum vitae.

THE WITNESS: I will.

BY MR. FARRELL:

Q. The next category I want to talk about before we jump

into the substance is methodology. Help me and help the Court understand when an epidemiologist goes about to do their job what is the methodology that you employ that is -- and I don't mean you. I mean the field of epidemiology, is there a standard methodology that you use in your practice?

A. Yes.

Q. And, in fact, do you teach this methodology in graduate schools?

A. I do.

Q. And so, will you tell the judge briefly and broadly. Because we're going to apply that later. The methodology that epidemiologists employ?

A. Yes. We conduct data analysis and apply statistical and epidemiological methods to try to uncover patterns in the data associations. And then we look at the broad range of literature that's available and apply well-developed and standard sets of factors to the broader range of literature to try to determine if those associations are causal.

Q. So, that's what you told me before. I'm going to try to unpack that a little bit. So, is it fair to say that what epidemiologists do is you identify exposures?

A. Yes.

Q. And then you try to determine causal associations with related harms?

A. That's right.

Q. So, there's a lot to unpack in that particular thing. Let's talk for a second about the difference between an association and something -- and an association that is causal. Is there a difference between those two words?

A. Yes. In any epidemiological study, including randomized controlled trials, what you estimate are associations. And then you try to figure out which of those associations are causal and which of them reflect two factors that are just correlated, that there's no actual causal association.

Q. So, let's dig a little bit deeper on that. If you have five studies of five cohorts, or five separate populations, is it possible that each of those five studies may identify an association, but it doesn't reach to the level of causal?

A. Any study alone, it's difficult to reach a causal conclusion just based on one study. You really need to look at a broader range of literature.

Q. And so, in order to get to -- from an association to causal, what do -- what factors do epidemiologists use to reach that analysis?

A. Sure. We look for things like is there a consistent relationship? Is this relationship observed in different populations, observed in different times with independent researchers? So, that's a really major one for us.

We also look for things like dose response. If there's

more -- as the exposure gets higher, do you see more of the outcome? We look for the strength of the association. We want to make sure that there's a biologically plausible reason why the exposure should be related to the outcome based on what we know about biology and sociology.

So, those are the types of factors we look at. We also look at have you ruled out alternative explanations? You know, what are the alternative explanations for this association? And is there actual evidence that would rule out the alternative to a causal explanation?

Q. Okay. And do you teach these factors to your students?

A. Every first year Masters student.

Q. And is there a common framework in which you teach these factors to students?

A. A lot of times we use Bradford Hill's classic paper as the kind of framework for walking through those types of criteria.

Q. Who is Bradford Hill?

A. Bradford Hill was an epidemiologist and medical statistician who really did some of the foundational work in establishing that smoking was a cause of lung cancer in the 1950s and 1960s. He really pioneered a lot of epidemiological methods that established that association.

And the methods that we would use to separate -- you know, some people said smoking is just correlated with lung

cancer and he developed these factors that allowed us to come to a causal conclusion, that it was indeed a causal factor.

Q. Okay. Now, let's talk briefly about your references and reliance materials. Have we asked you to use your skills as an epidemiologist to analyze and draw causal associations between opioid exposure and opioid-related harms in Huntington-Cabell County, West Virginia?

A. Yes.

Q. And the things that you relied upon, can you give the Court a listing in numerical order of your reference materials?

A. Not by memory.

Q. They're extensive, are they not?

A. They are.

Q. And you have also published a report, have you not?

A. Yes.

Q. And the report, quite frankly, is rather extensive. I think my colleagues would agree that it's dense.

A. Yes.

Q. It's a dense document.

MR. FARRELL: Judge, what I would ask to do is, I would ask to distribute a copy of the report, the reliance materials and references. I don't intend to admit them in the record, but I would suggest that having reliance on this

so that the Court, the witness, and the parties can see the numbers and the data may be of assistance and an efficient way to elicit testimony.

So, with your permission, may I approach and distribute?

THE COURT: Is there any objection to that?

MR. HESTER: Your Honor, I don't have any objection to providing it to the witness or to the parties. I don't think it should go to the Court, is my understanding, but unless --

THE COURT: Does everybody agree with that?

MS. MCCLURE: I join.

MS. HARDIN: Yes, Your Honor.

THE COURT: All right. Well, I guess everybody gets it but me, Mr. Farrell.

MR. FARRELL: This means I've got extra copies for people.

May I approach?

THE COURT: Yes.

BY MR. FARRELL:

Q. Okay. So, for purposes of creating a record, Exhibit B-1 is your reference materials and can you flip to that and tell the Court how many pages of reference materials you have listed of literature?

A. And this is what page?

Q. It's Exhibit B-1. And the answer may or may not be 48 pages.

A. B-1.

Q. Yes, Exhibit B-1.

A. It is 48 pages.

Q. Yes. And there are 840 separate line items, are there not, in your reliance materials?

A. Yes.

Q. Okay. So, with ten minutes before the first anticipated break, I think -- no? We're going to jump right into a -- we're going to jump right into it with the gateway effect.

THE COURT: I think 40 minutes before the first break, Mr. Farrell.

MR. FARRELL: 40 minutes and yes, Your Honor.

BY MR. FARRELL:

Q. We're going to jump right into the first topic. I'm just going to jump right in. You're familiar with the OIG Report from 2019?

A. Yes.

Q. The Office of the Inspector General. And I'm not going to have you talk about anything except for Page 1. All right? And I'm going to use this as a vehicle for us to talk about our favorite topic, which is the gateway effect. You have, in fact --

MR. HESTER: Your Honor, may I object? I'm not aware that this witness listed the OIG Report in her reliance materials.

THE COURT: Did she or did she not?

MR. FARRELL: I don't know, Judge. This is entered into evidence and I'm simply going to ask her if there's an epidemiological basis in support for the reference point in the OIG entered into this case.

MR. HESTER: I think --

THE COURT: Well, if she used it as one of the materials she relied on, can't she talk about it?

MR. HESTER: She did not.

THE COURT: She did not?

MR. HESTER: Did not. It's not listed in her reliance materials, Your Honor, and I do not believe she offered any opinion related to this OIG Report.

MR. FARRELL: Judge, I'm not asking if she's relied upon it. I'm going to ask her whether she agrees with it.

MR. HESTER: Well, Your Honor, it seems to me that goes beyond the scope of her expert opinions if it's not been disclosed to us that she was going to offer an opinion on this OIG Report. This is the first time we've heard of this.

MR. FARRELL: I'm simply trying -- let me see if I

can back up and lay a better basis.

BY MR. FARRELL:

Q. Dr. Keyes, do you intend to -- or do you have an opinion whether exposure to prescription opioids has a causal association with the initiation of heroin?

A. Yes.

MR. HESTER: Object as vague, Your Honor.

THE COURT: I'll overrule that objection, but what about the reference to the OIG Report or whatever that is?

MR. FARRELL: I was really just trying to cite it because it says exactly what she says and it cites the same thing she cites. So, I was trying to use the defendants' exhibit to bolster my witness's testimony.

MS. HARDIN: Objection, Your Honor. That's improper. That's improper corroboration of his own expert. His expert is here. He can ask his expert what his expert thinks, but he doesn't corroborate with a separate document.

THE COURT: Yes. Mr. Farrell, you'll have to get at it some other way.

MR. FARRELL: Okay. All right.

BY MR. FARRELL:

Q. So, in your analysis have you relied upon the medical literature to support your opinion as to a causal association between prescription opioids and heroin?

A. Yes.

Q. And, in fact, do you believe that there is a causal connection between prescription opioids and heroin?

A. Yes.

Q. Do you believe it is factually established in the medical literature?

A. Yes.

Q. So, if you were to tell the Court and name some of the most prominent articles that establish this, which would be the first of your choosing?

A. I would point to a consensus statement perhaps by the Association for Schools of Public Health, which is an organization of more than a hundred schools of public health across the country.

Q. Okay. So, let's start with that. Let's say it again slower this time. This is -- what is -- this is a professional organization?

A. Yes.

Q. And what is the name of it?

A. The Association For Schools of -- there's another P. It's Public Health and another P.

Q. Well, I'm not going to have you guess.

MR. FARRELL: Judge, I also have several pages of a demonstrative that I previously provided to the defendants and, with your permission, I'd provide you a copy and publish to the witness.

BY MR. FARRELL:

Q. For reference point, we're going to be looking at Page 11. So, it's the Association of Schools and Programs in Public Health?

A. Programs. That was the P I was missing.

Q. Or ASPPH2019. Will you tell the Court what this association is?

A. This is an Association of Schools of Public Health across the country. There's more than 100 schools of public health that are a part of it, including West Virginia University and Columbia University.

Q. Okay. What about -- what other prominent schools of public health are members, Johns Hopkins?

A. Yes.

Q. Harvard? Yale?

A. I believe so.

Q. Stanford?

A. I don't have them all memorized, so I don't want to -- I don't want to have -- say anything that's potentially incorrect, but there's a lot of schools that are involved.

Q. Okay. And so, what is the consensus statement from the Association of Schools and Programs in Public Health?

A. I think this quote that is on the demonstrative is a good summary of the consensus of epidemiologists on this topic.

MR. FARRELL: With the Court's permission, I would like her to read it into the record.

THE COURT: You may do so.

Is there any objection?

MR. HESTER: No objection, Your Honor.

THE COURT: All right. You may do so, Dr. Keyes.

THE WITNESS: Sure. The tremendous expansion of the supply of powerful high potency, as well as long-acting prescription opioids led to scaled increases in prescription opioid dependence, and the transition of many to illicit opioids, including fentanyl and its analogs which have subsequently driven exponential increases in overdose.

And there's a second statement. Opioid Use Disorder is caused by repeated exposure to opioids.

BY MR. FARRELL:

Q. So, Dr. Keyes, do you concur that this is a consensus statement from all of the schools that belong to the Association of Schools and Programs in Public Health?

A. Yes.

Q. In your opinion, is this statement a fact?

MR. HESTER: Object to the form.

THE COURT: Sustained. You can rephrase it, Mr. Farrell.

BY MR. FARRELL:

Q. Do you believe this statement is true?

A. I believe that the evidence in the medical literature is -- overwhelmingly supports the validity of this statement.

Q. Now, one of those pieces of literature is an article that you cite repeatedly called Cicero. Are you familiar with the Cicero study?

A. I am.

Q. And will you tell the judge what is the Cicero study?

A. Cicero colleagues collecting data on a large number of individuals who are in treatment for drug use disorders and interviewed them extensively using well-validated instruments on their histories of various drugs.

Q. And you're going to have to forgive me here, but I don't know that I can read this small. But the Cicero opinion -- or article, where was it published?

A. JAMA Psychiatry.

Q. And that's JAMA, Journal of American Medical Association?

A. That's right.

Q. Now, in the Cicero article there is a data graph that you reference. Would it be helpful for you to see the data graph and show the judge the findings in Cicero?

A. Yes.

MR. FARRELL: And, Judge, with your permission, I would like to show Demo Exhibit 12.

THE COURT: You may do so.

BY MR. FARRELL:

Q. So, this is, for the record, Figure 1 from the Cicero article and Figure 1 is the -- the title of it is Percentage of the Total Heroin Dependent Sample That Used Heroin Or a Prescription Opioid As Their First Opioid of Abuse. And will you explain to the judge what this table demonstrates and why it supports your conclusion that there is a causal association between prescription opioids and heroin?

A. Yes. So, on the x-Axis, which is the horizontal axis, the authors separated the respondents by the decade in which they first used opioids and then interviewed them about the sequence with which they used opioids.

And you can see that in -- for people who started using drugs in the 1960s, and in the 1970s, and in the 1980s, the square, heroin, is much higher than the circle, prescription opioid.

So, many more people started with heroin as their first opioid in the 60s, 70s and 80s. Once you crossed in the 1990s and 2000s, you can see the line flips and now the circle's on top and the square's on bottom, which indicates that, as of the 2000s, many more people who ended up using heroin started with a prescription opioid before they used heroin.

THE COURT: These are all heroin dependent

individuals?

THE WITNESS: Yes.

THE COURT: So, the whole study?

THE WITNESS: For this analysis, yes, they're all heroin dependent.

BY MR. FARRELL:

Q. And is the Cicero study relied upon and viewed as reliable in the field of epidemiology?

A. Yes.

Q. Have you seen any literature which brings to -- or substantially challenges the validity of the Cicero study?

A. No. And, in fact, there are many other studies. The Cicero study is, you know, one of the largest and, you know, goes back the furthest, but there are many studies that I cite in the report that find that 70-80 percent of people who end up using heroin begin with prescription opioids and that that started in the 2000s.

Q. And, in fact, that's the exact statistic cited often by the National Institute of Health, is it not?

A. It is. It's on the National Institute of Drug Abuse website.

Q. Now, in addition to that, the New England Journal of Medicine has a review article written by Compton. Are you familiar with that article?

A. I am.

MR. FARRELL: Now, this article is a little more detailed. And so, I'd like to, with the Court's permission, provide a copy to counsel, the witness, and to the Court unless there's an objection.

MR. HESTER: Well, the only objection is that the protocol among the parties is that we would exchange lists of exhibits to be used with witnesses at least a day in advance and we were not provided with any exhibits to be used with Dr. Keyes.

MR. FARRELL: I'm not publishing any of this. This is -- I'm just going to ask her questions. I was just being courteous. I can do so without it.

MR. HESTER: Well, it seems to me, Your Honor, the spirit of the protocol is that if Mr. Farrell is going to be using articles with the witness, we would have had a chance to know in advance which articles those would be so we'd have some opportunity to prepare.

THE COURT: Yeah. Aren't they entitled of notice of what you're going to use because it would be a fundamental element in the preparation of the cross examination, I would think, potentially.

MR. FARRELL: I don't know that I disagree with any of that, Judge. I don't know that -- this witness has been deposed four times. This is in her report. This is not undiscovered territory that she's going to say the

gateway effect is supported by Cicero and Compton.

THE COURT: Well, I'm going to let you go ahead and then I'll decide the extent, if at all, that I'm going to consider it. This is a factor I think and -- well, go ahead.

MR. FARRELL: I'll make it -- I'll make it easier.

BY MR. FARRELL:

Q. The New England Journal of Medicine is one of the articles that supports your conclusion that there is a causal association between opioids and heroin; agreed?

A. Agreed.

Q. Now, in case there's any doubt -- and I'm going to test your memory. How many -- what other sources are you aware of that are relied upon by epidemiologists in the field that support the causal association between prescription opioids and heroin?

A. You know, just knowing that 70-80 percent of people who use heroin start with prescription opioids is kind of one piece of the puzzle, but there's also a lot of prospective studies where they take people who use prescription opioids and people who don't use prescription opioids and follow them forward to see what the risk of heroin initiation is.

And I think Banerji, which is cited in my report, is a good example of that. They took Veterans Administration data, which is very well characterized, and it was over

3,000 people. And they followed veterans who, you know, were between 40 and 60 years old, followed them forward, and some of them had used prescription opioids, some of them haven't, and they looked to see the time to first heroin use and whether that was different between the two groups.

And the group that used prescription opioids was more than five times more likely to use heroin. They then compared the strength of that association to other risk factors like other drug use, marijuana use, cocaine use, stimulant use. And prescription opioid use was by far the strongest risk factor for transition to heroin compared with other kinds of drugs, compared with demographics that are also related to heroin initiation.

The five times more likely in the prescription opioid use was the strongest risk factor. And so, that's often cited as a strong piece of the puzzle that we use to come to these causal conclusions because it meets that strength of association piece that I spoke about earlier. Temporality. You know, it was established that the prescription opioids came first. And then it's consistent with all these other studies. And so, epidemiologists use that evidence to come to causal conclusions.

Q. I'm going to try to use this as a rubric or as a framework. Can you bring up Page 1 of the demonstrative?

MR. FARRELL: May I approach, Judge?

THE COURT: Yes.

BY MR. FARRELL:

Q. All right. On the left-hand side, I've attempted to capture instead of writing on a chalkboard the factors that you have mentioned that come from the Bradford Hill rubric. Have I written down accurately your testimony today about the various factors that go -- that an epidemiologist uses when trying to determine whether an association is causal?

A. Yes.

Q. Okay. All right. So let me see if I can get this to work. Rx opioids. And then I'm going to use an empty blank and I'm going to write heroin.

And so, what we're looking for is if there is a -- an association between prescription opioids and heroin, correct?

A. Yes.

Q. And in some of the studies that you mention it talks about that they can find association, but not causal, correct?

A. Some of the studies say that, yes.

Q. So, we'll get that in a minute like for Ghertner. What I want you to do is to explain to the judge why in this case you believe you can go from an association to causal?

A. That's what epidemiologists do. So, any one study usually is not sufficient evidence to decide whether an

exposure outcome relationship is causal. But I take a step back and look at the entire body of the literature and so --

Q. You do so by applying the key factors, correct?

A. I do.

Q. And looking at the key factors, number one, dose response relationship, we've talked about that, correct, with your -- with your testimony so far?

A. Yes. And there are other studies that I can speak to, as well, on that topic, if you'd like me to.

Q. We'll get there, I think, with the other ones.

A. Okay.

Q. But we also have the temporal relationship, which is number 2.

A. Uh-huh.

Q. I'm just creating a record now. 3, strength of association, correct?

A. Yes.

Q. 4 is consistency?

A. Yes.

Q. 5 is biologic plausibility?

A. Yes.

Q. And 6 is consideration of alternative explanations?

A. That's right.

Q. Now, I think that we have talked about everything except for number 5 with regard to whether or not there is a

causal association between prescription opioids and heroin. Do you have -- have you performed an analysis or tried to identify from the medical literature whether or not there's a biologic plausibility for a causal relationship between prescription opioids and heroin?

A. Yes.

Q. And what is your determination?

A. It is biologically possible.

Q. And that's from the epidemiology literature?

A. Yes. They have similar pharmacological properties.

Q. All right. Now, in addition to exposure to prescription opioids and heroin, you also undertook to measure the exposure in Huntington-Cabell County, correct?

A. Yes.

Q. All right. So, let's talk for a second about what that means. So, we have exposure and we have harm. So, in order to make that measurement or make that causal association, we have to define the exposure. Have you undertaken the task as an epidemiologist to look at exposure to prescription opioids across the country?

A. Yes.

Q. Have you also done so yourself and seen in the medical literature the same analysis at a state level?

A. Yes.

Q. And have we asked you to do so on behalf of

Huntington-Cabell County?

A. Yes.

Q. And would you please tell the Court your findings?

A. I looked at the literature on the distribution of prescription opioids and the trends over time, which is my particular area of expertise. Nationally, at the state level, and in Cabell and Huntington, and what I found was that there was an enormous increase in the supply of prescription opioids nationally.

In West Virginia, it was higher than it was nationally. And in Cabell County, it was higher than it was in West Virginia. So, if you kind of think about those three geographic areas, there was an increase in the prescription opioid supply in all three, but the concentration of that increase was much greater in Cabell than in the rest of the country.

Q. Now, is this your opinion or is this an epidemiological fact?

A. It's based on the epidemiological data.

Q. All right. So, if we say exposure, is exposure -- let's try to find another word that helps me understand. Is supply another word for exposure?

A. Yes.

Q. All right. Now, other than the relationship from prescription opioids to the initiation of heroin, have you

undertaken the task to try to determine whether or not there is a causal association between exposure or supply of prescription opioids and harms?

A. Yes.

Q. And in your analysis have you reached to a reasonable degree of epidemiological certainty an opinion in this regard?

A. Yes.

Q. Will you tell the judge what exposures or supplies of prescription opioids, what causal associations you found of related harms in Huntington-Cabell County?

A. I reviewed the literature and compared them to all of the key factors that we look at and they all point in one direction and that is that increased exposure to the supply of prescription opioids caused harms in Cabell-Huntington.

Q. Now, let's identify which harms you have identified. Can you list them for the judge? And we'll talk about them each individually?

A. Sure. Opioid Use Disorder. I would also list diversion and non-medical use. I would list hospitalization and overdose. I would also list, although we've already talked about it, transition to other opioids, in particular, heroin and fentanyl.

Q. How about -- how about morbidity or deaths?

A. Yes. I would also list death.

Q. How about NAS?

A. Yes. I would list NAS, as well.

Q. Have you also looked into related harms for IV injections, such as endocarditis, HIV and hepatitis?

A. Yes.

Q. And how do we classify those IV-injectable types of injuries? Is there a label or a short word for me to say?

A. Bloodborne diseases, I think, would be the common shorthand.

Q. All right. So, in your final analysis do you have an opinion whether or not exposure or supply of prescription opioids has a positive causal association with Opioid Use Disorder?

A. Yes.

Q. Diversion or non-medical use of opioids?

A. Yes.

Q. Hospitalizations?

A. Yes.

Q. Overdoses?

A. Yes.

Q. Death?

A. Yes.

Q. Neonatal Abstinence Syndrome?

A. Yes.

Q. And bloodborne diseases?

A. Yes.

Q. Such as endocarditis, HIV and hepatitis?

A. Yes.

Q. And this is your specific -- your opinion is specific causal association to exposure and supply of prescription opioids to the peoples of Huntington-Cabell County, West Virginia and these related harms?

MR. HESTER: Object as leading.

THE COURT: Well, the question is leading, but I will allow her to answer it.

THE WITNESS: Yes.

BY MR. FARRELL:

Q. Putting it into other words -- well, and we'll come back to this in the end, but what I would like you to do now is I would like for you on a technical basis to let's now go through each of these key factors 1-6 from the medical literature from your analysis and tell the judge why you believe that the relationship that we've just discussed for each of these items is not just an association, but causal.

Let's start with dose response relationship. Will you please tell the Court your assessment and analysis?

A. Sure. So, there's a number of studies in the literature that I've looked at, dose and duration, which are two key factors that we look at when we're looking at exposure to prescription opioids.

Duration can be considered a measure of dose because, as the duration goes on, you're exposed to a higher dose. This has been shown repeatedly in the epidemiological literature with regard to Opioid Use Disorder, both among people who are taking a prescription and among people who are using prescription opioids non-medically.

For example, I could point to an Edlund study from 2014.

Q. Let's stop for a second.

A. Okay.

Q. This is where the court reporter is going to be endeared.

A. I'm trying to go slowly.

Q. Will you spell Edlund?

A. E-d-l-u-n-d.

Q. And do you know which journal it was published in?

A. I don't remember off the top of my head.

Q. I'm sure I have that. Somebody will provide a reminder very quickly.

If I showed you the article, would that help refresh your recollection?

A. It would.

MR. FARRELL: Judge, may I approach?

THE COURT: You may.

THE WITNESS: It is published -- I'm sorry.

THE COURT: Take it back and then ask her.

MR. FARRELL: Yeah.

You got it?

THE WITNESS: Yes.

MR. FARRELL: Okay.

THE COURT: Did that refresh your recollection, Dr. Keyes?

THE WITNESS: It did.

BY MR. FARRELL:

Q. Okay. And so, where was the Edlund article published?

A. The Clinical Journal of Pain.

Q. Yes. Now, will you tell the judge the significance of the Edlund article?

A. It's one article that established a dose response relationship between use of prescribed opioids and these are people who had a prescription in a medical record and development of Opioid Use Disorder. It showed essentially that with each increase in the dose and the duration of opioid use there is a higher incidence, new onset of Opioid Use Disorder.

In fact, for people who are taking opioids for more than 90 days at a high dosage, those individuals were 122 times more likely to develop Opioid Use Disorder compared to people in the same medical system who didn't use a prescribed opioid.

Q. Now, 122 times, I would like to build into this a little bit, a little bit deeper, and I have screwed this up, I fear, but I am going to try anyway.

So, the Edlund article, what year is it from?

A. 2014.

Q. Question number one. Is this article relied upon by epidemiologists in your field when performing research on opioid use and Opioid Use Disorder?

A. Yes.

Q. Is it respected?

A. Yes.

Q. Is it subject to any underlying question of veracity?

A. Not that I'm aware of.

Q. Now, the essence of the Edlund article was that it showed that there was a -- it quantified a factor of 122 times what?

A. More -- 122 times greater incidents of Opioid Use Disorder.

Q. If what?

A. If you used prescription opioids for more than 90 days at a high dosage.

Q. High dosage. Now, did it also measure medium dosage?

A. Yes.

Q. And what did it find?

A. I believe those at a medium dosage were about 15 times

more likely.

Q. And did it measure low dosage?

A. I actually believe the low dosage was 15 times and the medium dosage was about 26 or 27 times.

Q. Would it help to refresh your recollection or are you good with those numbers?

A. I think it's in that ballpark. We can -- I have it in my report. I can pull it up and look at it very quickly.

Q. No. Ballpark is good enough for me to make this -- to make this.

Now, I know I struggle with this language sometimes but is this -- does this quantify the relationship between opioid exposure and Opioid Use Disorder?

A. It does.

Q. All right. So, do you recall the Bradford Hill, the guy that wrote the first article on these factors?

A. I do.

Q. Did he also attempt to quantify the association between smoking and cancer?

A. And lung cancer, yes.

Q. And what -- what magnitude did he determine? What was the relationship in that case?

A. In his original 1950 case control study, the magnitude of the relationship was 13. So, smokers were 13 times more likely to develop lung cancer than non-smokers.

Q. And what -- at the time and today, what is 13 times considered? Is there an adjective?

A. Very large association.

Q. Would you call it strong?

A. I would.

Q. Is it actually referenced as strong in some texts and literature?

A. The relationship between smoking and lung cancer is generally considered to be strong.

Q. And if 13 times greater risk is considered strong, what would 122 times be considered?

A. Extraordinarily strong.

Q. Okay. What else? I'm asking for some adjectives.

A. I have rarely seen a strength of association in the epidemiological literature that is 120 --

THE COURT: I'm a little bit confused. 122 times what? I missed that.

THE WITNESS: So, the people who are using opioids, that are prescribed opioids, who are using them 90 days or more at a high dosage, their risk of developing Opioid Use Disorder is 122 times greater than people who don't use opioids.

THE COURT: And you explained that clearly awhile ago and I didn't catch it and you had to do it again, right?

THE WITNESS: That's -- I'm -- I'm a professor.

This is what we do.

MR. FARRELL: It took me two times.

BY MR. FARRELL:

Q. Now --

A. This study also establishes temporality, which is really important, and I think Edlund did that really well, Edlund and colleagues, not to ignore that there were other co-authors, probably other epidemiologists.

Q. So now, I'm going to go back to what I was told to do before.

THE COURT: I think this is a good time for a break, Mr. Farrell, and we'll be in recess for about ten minutes.

You can step down during the break.

THE WITNESS: Thank you very much.

(Recess taken)

(Proceedings resumed at 2:36 p.m. as follows:)

THE COURT: Dr. Keyes, if you'd come back up, please.

BY MR. FARRELL:

Q. Welcome back, Dr. Keyes. So I think we finished -- I think we finished up with the Edlund piece, so I'm just going to put one little checkmark there.

The second one I wanted to talk about was Ghertner. And this is a 2019 article. And are you familiar with the

Ghertner article?

A. Yes.

Q. That's G-h-e-r-t-n-e-r. Is this a dose response relationship factor that you relied upon?

A. It is.

Q. Okay. Will you tell the Judge the results of the Ghertner study?

MR. HESTER: Your Honor, may I object again? We weren't given a list of any documents that were going to be used with this witness. And this -- we're now putting up a study that I didn't know would be used today for purposes of the direct examination.

MR. FARRELL: I'm not putting up any slides.

MR. HESTER: Well, I know but he's putting up an article that ideally I would have read so I would know what was in it if it was going to be used this way.

THE COURT: Well, shouldn't you have put them on notice of the things that you were going to question him about that were the basis for her opinions?

MR. FARRELL: Well, Judge, this is our Rule 26 disclosure. This is in her report. This has been deposed. This is the basis for her opinions.

THE COURT: This is in her report, references to this?

MR. FARRELL: Yes, sir.

THE COURT: I'll overrule the objection and let you go ahead.

MR. FARRELL: Now, to be fair, her report is quite extensive. And, so, I'm not going to be going through all 48 pages.

THE COURT: Well, let's get rolling here. We need to get some people out of town this afternoon if we can.

MR. FARRELL: Yes, sir.

BY MR. FARRELL:

Q. So will you tell the Court briefly how the Ghertner opinion supports your analysis finding a causal association between prescription opioids and related harms?

A. So this analysis used data on the amount of prescription opioids distributed in U.S. counties, and correlated the amounts by county with the level of opioid-related hospitalization.

And they found that each increase in the distribution of prescription opioids by county was associated with about four percent additional opioid-related hospitalizations.

So this study showed more supply, more hospitalizations. And that relationship was dose response.

Q. Okay. Now, for temporal relationship, will you tell the Court what evidence you found to support your opinions based upon the key factor of temporal relationships?

A. So for temporal relationships what we're really looking for is people who didn't have a history of opioid use disorder before they were prescribed opioids, for example, or were heroin-naive before they started using prescription opioids.

And we want to establish that the cause precedes the effect. And that's well documented in the epidemiological literature that that means 80 percent of people used prescription opioids before they used heroin, there is a number of studies that show that among people who have never had an opioid use disorder, a portion of those who are prescribed opioids go on to have an opioid use disorder and other -- a consistent body of evidence that shows that the cause precedes the effect.

Q. Not to be cute, but is it difficult to acquire opioid use disorder if you're never exposed to opioids?

A. Very difficult.

Q. Versus if you're exposed to opioids, there is a temporal relationship with the onset of, of opioid use disorder?

A. That's right.

Q. Same thing with, say, mesothelioma. It's difficult to get mesothelioma without exposure to asbestos?

A. Correct.

Q. Versus lung cancer where you can get lung cancer

without smoking. But if you smoke, there's a higher, a higher relationship?

A. Well, and I think there's an analogy here too because there are people who use heroin who have never used a prescription opioid. And there are people who use prescription opioids who don't go on to heroin use.

It's a risk factor just like smoking is a risk factor for lung cancer where if you use a prescription opioid, that is by far the strongest risk factor for development of opioid use disorder and heroin compared to not using prescription opioids. But it's a risk factor.

Q. So is there medical literature to support your analysis under the temporal relationship factor?

A. Yes.

Q. The next factor, strength of association. Would you tell the Judge how the strength of the association weighs into your analysis regarding causal associations?

A. Yes. I think some of the studies that we've already mentioned demonstrate how strong this association is. And, generally, I think there's consensus in my field that the strongest risk factor for opioid use disorder is prescription opioid exposure.

Q. The next factor is consistency. What does consistency mean and how does it apply to this case?

A. Consistency means do you observe the same relationship

in -- do independent people, independent research groups, independent epidemiologists, and independent populations, you know, do you observe the same relationship over and over and over again in different studies that are conducted in different ways.

Q. We've discussed biologic plausibility. But just to re-emphasize, have you examined whether or not the medical literature contains references to the biological plausibility in support of your analysis?

A. Yes.

Q. What about the consideration of alternative explanations? I think this deserves a little more attention. Will you explain to the Judge your analysis of that factor?

A. Yes. So if you're looking at, you know, does prescription opioid use cause harm, the question is: Well, what other factors in the environment could plausibly explain that relationship other than prescription opioids?

Certainly one that's been discussed a lot is economic conditions. And, so, you know, you might say, well, it's not the prescription opioids. It's areas with economic deprivation and people who are more vulnerable to develop drug addiction in those areas.

So that's been a big focus of a lot of the scientific literature trying to tease apart cause and effect with

respect to something like economic conditions as an alternative explanation.

And what's been demonstrated in well-done studies -- and I would point to Ruhm for example, R-u-h-m, as a paper that's cited in my report who demonstrated that economic conditions really, when you analyze the data in a rigorous way, play a relatively small role in the opioid-related harms that we've seen in the United States over the last 15 years.

He captured economic conditions with a number of different really reliable metrics, and I think in his abstract and study suggests that less than 10 percent of the overdose crisis that we've seen in America can be attributed to something like economic conditions.

And by far, the most reliable and strongest determinate of the overdose crisis is the availability and price of prescription opioids.

Q. All right. Are these the only six factors in the Bradford Hill analysis?

A. Bradford Hill had other factors in his 1965 paper. And, so, yes, there were other -- Bradford Hill had other factors in that paper.

Q. All right. So to be fair to the Court and to opposing parties, is there a balance of literature out there that would raise significant dispute with your conclusions?

A. Not that I'm aware of.

Q. At this time, I'd like to kind of switch over and talk about some of your data findings as we discussed yesterday as you built upon Dr. Smith. And I'd like to go first to Page 2 which is Figure 3.

Dr. Keyes, this is Figure 3 from your report. Do you recognize it?

A. I do.

Q. Give us a second for the little things to turn off. Okay.

Will you orient the Judge -- first, what is it that we're looking at and where did you get the data from?

A. So this -- these are data on overdose death rates for all drugs, so whether opioids or something else.

The red line is the overdose death rate age-adjusted by year for the whole country. The green line is for West Virginia. And the blue line is for Cabell County.

And I obtained these data from the Centers for Disease Control, publicly available information on causes of death in the United States.

Q. Now, I'm going to apologize. I'm going to have to get a little technical for the record.

The age-adjusted rate on the X axis, what does that mean?

A. That means that it is the number of overdoses per

100,000 people in each of these years, and it's adjusted for age.

And, so, if two counties have really different -- you know, if one county had a lot of older folks and one, another county had a lot of younger folks, you would expect there to be differences in the overdose rate just because there is differences in age.

So this adjusts out any compositional differences in a county or a state with respect to the age of the population.

Q. So let me see if I can get this clean.

Do you have an opinion as to whether or not there is an opioid epidemic in the United States?

A. I do.

Q. What is that opinion?

A. There is an opioid epidemic in the United States.

Q. And, respectfully, is there any epidemiologist in the country that you know of that would disagree with that, that opinion?

A. I don't know any epidemiologist who would disagree.

Q. Now, do you also believe that there is an opioid epidemic in West Virginia?

A. I do.

Q. And do you believe there is presently an opioid epidemic in Huntington/Cabell County, West Virginia?

A. I do.

Q. Looking at this data, does it demonstrate that the overdose death rates for all drugs in the United States has gradually increased over time?

A. Yes.

Q. And does your data finding show that for the most part, West Virginia has always been in excess of the national rate?

A. For most years, yes.

Q. And that in Cabell County, West Virginia, Huntington/Cabell County, West Virginia, the rate is in excess of the state which is in excess of the nation?

A. That's right.

Q. Now, you'll see that there's this sudden spike of overdose death rates from 2013 on. Have you conducted an analysis to determine within the "all drug" classification what that is?

A. Yes.

Q. I'd like to go to the next slide. I'm sorry. Before we get to that one, let's go back to the one we were just at to finish. Go to the next one for the state. Yep, that one.

So do you recognize Figure 6?

A. Yes.

Q. What is Figure 6?

A. That is a map of West Virginia. And I've colored in

each county with their overdose death rate per 100,000 people average from 2014 to 2018.

Q. So we've already established that West Virginia is higher than the national average. This is a heat map of the State of West Virginia by county; correct?

A. Yes.

Q. And I'm not going to quiz you too much about your geography, but I think you know the answer. Is there one particular county here that is darker than the others?

A. Cabell County.

Q. And that's in the left-hand corner; correct?

A. Yes.

Q. And why is it darker than the other counties?

A. Because it has the highest rate of overdose.

Q. So is it fair to say that for the true overdose deaths that Cabell County has the highest rate in the State of West Virginia, and that West Virginia is continuously in excess of the national average?

A. Cabell County is -- I believe I said in my report I believe it's in the top five counties in the country in terms of overdose deaths.

Q. All right. Now, we can go to the next slide. This is slide 4.

And the difference between the Figure 3 and Figure 7 is what, Dr. Keyes?

A. This, this is just sub-setting the "all overdose" category to all overdoses that included opioids.

Q. And, so, before we talk about all overdoses, this is now a subset of just all opioids. And are the trends consistent with what you saw for all overdoses?

A. Yes.

Q. And, again, Cabell County is in excess of the State of West Virginia which is in excess of the national trend. Agreed?

A. Generally, yes.

Q. All right. Now let's go to Figure 8. Do you recognize Figure 8?

A. I do.

Q. And what is Figure 8?

A. That is an estimate of the overdose death rate for prescription opioids.

Q. And where did you obtain this information?

A. This is an estimate that I created based on the CDC's numbers.

Q. And, again, what, what are your findings in this regard?

A. Generally, you see similar patterns where West Virginia is higher than the country. And, generally, although there's a little bit more variation for prescription opioids, Cabell County is consistently higher than West

Virginia.

Q. Now, go to Figure 9. And what is Figure 9?

A. That is the Cabell County overdose death rate by type of drug.

Q. And where did you get this data from?

A. From Dr. Smith.

Q. Okay. And please explain to the Court what your analysis of Dr. -- of the data compiled by Dr. Smith reveals.

A. This reveals that in Cabell County throughout much of the 2000s overdoses in the county were primarily driven by prescription opioids.

Then in the -- after about 2012, '13, '14, heroin overdoses started to increase. And then by 2015 we really saw an exponential increase in fentanyl overdoses.

Q. Now, go to Figure 10, please. What -- do you recognize Figure 10 from your report?

A. I do.

Q. What is it?

A. This is the rate per 100,000 hospital births of infants diagnosed with Neonatal Abstinence Syndrome.

Q. The Court has already heard the description of Neonatal Abstinence Syndrome from Dr. Werthammer, so we won't go into detail about it. But I do want you to describe for him what your findings are for the difference between the national

numbers and West Virginia numbers and then Cabell County's numbers.

A. Consistent with the other trends that we observed, West Virginia is generally higher in terms of NAS than the country, substantially higher. And Cabell County is generally higher than West Virginia as a whole.

Q. So when you were comparing Neonatal Abstinence Syndrome from Figure 10 in 2016, 2017 will you tell the Court -- read into the record what is the rate per 1,000 hospital births as documented in Figure 10 for Cabell County.

A. 62.3 per 1,000 hospital births are babies diagnosed with NAS.

Q. And what is the rate for 100,000 hospital births for the State of West Virginia?

A. 56.2.

Q. And what is -- in the same time frame, what is the rate in the United States?

A. Seven.

Q. So what factor greater is that?

A. It's about seven to nine depending on the location.

Q. All right. Go to the next slide, please. This is Figure 13. Do you recognize -- I'm sorry, Figure 12. Do you recognize Figure 12?

A. Yes.

Q. What is Figure 12?

A. This is opioid-related hospital use.

Q. For which geographic area?

A. I believe this is West Virginia.

Q. And what does it indicate?

A. It indicates that hospital use for opioid-related reasons is increasing in West Virginia since 2009.

Q. Now, in general, so far, for all of these opioid-related harms, is it fair to say that we have seen an increase over time?

A. Yes.

Q. And is there a causal association between this increase in -- between what we have seen with the increase in time for these opioid-related harms and the supply or exposure of prescription opioids in Huntington/Cabell County?

A. Yes.

Q. And what is that association?

A. There's a causal association between the supply of prescription opioids in Cabell/Huntington and the increase in opioid-related harms.

Q. And that includes opioid-related hospital use in the State of West Virginia?

A. Yes.

Q. So, in general, the opioid-related hospital, hospitalizations in the state have been increasing since 2009. Agreed?

A. Agreed.

Q. And where did you get this data from?

A. This is from a dataset -- it's a statewide publicly available dataset called HCUP. It's Hospitalization Care and Utilization Project I think.

Q. Okay. Go to the next slide, Figure 13. Now, this is prevalence of opioid use disorder in the United States, West Virginia, and Cabell County. Would you please tell the Judge where you got this data from and how you came up with the numbers?

A. Sure. This is an estimate that I created for opioid use disorder. There's -- we have no census of people who have opioid use disorder in the country or in Cabell County, so we have to estimate it.

And I used a very reliable and well-documented set of methods to estimate the prevalence of opioid use disorder in Cabell County.

It starts with I think a pretty -- a method that I can describe well, which is if you know the probability that someone who has an opioid use disorder dies and you know the number of deaths, you can just do some simple algebra to figure out how many people have opioid use disorder. So that's kind of the, the baseline of the calculation.

So I looked in the medical literature. And in 2019 there was a meta-analysis that was published by a very, a

very well regarded group who conducts meta-analyses all the time. And they had, in fact, done this same meta-analysis several years before, but then updated it in 2019 with more papers.

And they looked at every single study that has taken a population with opioid use disorder and measured how many of them died of an overdose. And they meta-analyzed them, which means they took all the studies, put them together, and got an average.

And, so, I took that meta-analytic estimate of the probability that you die of an overdose if you have opioid use disorder, which was .52 per 100,000 persons. And then I took the number of people who died of a drug overdose in Cabell County and I divided it by .0052.

Now, that's kind of the, the basic version. But you have to do some adjustments to that. You know, that's not going to be the end of the story, especially because after 2015, the death rate from using opioids began to increase. And that's due to the introduction of synthetic opioids.

So I thought, okay, I can't rely on this one estimate of the probability that you die given that you have opioid use disorder. I need two estimates.

So I had to figure out what's the probability that you die of an overdose if you use synthetic opioids.

So to figure that out, I used another epidemiological

method that is very well-established in the literature called an interrupted time series method.

And that's where if you have a sudden change in the environment, like the introduction of fentanyl, you can capitalize on that change to figure out how much the introduction of this new exposure of fentanyl changed the environment.

So I took the number of overdoses from 2013 to 2015 and figured out how much more of the overdose rate went up in just that very short period as an estimate of how much more likely you were to die given that fentanyl is now in the environment.

So I created two death rates; one for the probability that you die of an overdose given that you use opioids that don't have fentanyl, and one for if you do have fentanyl and then waited each year for the distribution of death that involved synthetic opioids versus not which is important because that then captures the increase in prevalence of synthetic opioids in overdoses over time.

So using those two estimates, and the waiting factor for the probability of synthetic opioids, I arrived at a prevalence of opioid use disorder by year.

Q. Okay. Dr. Keyes, have you been deposed on this subject matter before?

A. Yes.

Q. Okay. So I'm going to try to make the short version of this. You did a study based upon methodology used commonly by epidemiologists; correct?

A. Yes.

Q. And that you acquired information for every county in the United States to do an epidemiological sound study to determine the prevalence of opioid use disorder. Agreed?

A. I did.

Q. And you're in the process of getting this published in a peer-reviewed journal?

A. Yes.

Q. Which journal is considering it right now?

A. *Addiction*.

Q. So to use the simplest terms I can, you used a mathematical model that epidemiologists routinely rely upon in your field to perform a calculation to determine the prevalence of opioid use disorder by county across the country; correct?

A. Yes.

Q. And this is a graphic representation of the results for Cabell County, West Virginia, and national?

A. Yes. And I went a step further for Cabell County in particular.

I should clarify the study I have under peer-review is for the whole country. And I really wanted to make sure

that I had a reliable estimate for Cabell County.

And, so, in the course of writing my report, I reached out to people in Cabell County who are involved in data and who collect data on opioid use disorder. And I obtained another estimate from the health systems in Cabell and Huntington to --

MR. HESTER: Your Honor, two points.

First of all, this is the first time that we have heard that Dr. Keyes has a paper under peer-review that would be publishing this proposition around her estimates.

So it seems to us that if the plaintiffs are relying on a peer-reviewed study that she -- or that -- a study that she has under peer-review now that she's planning to publish, that should be produced to us.

Second point, Dr. Keyes is now going to be discussing an affidavit from a Todd Davies I believe. Mr. Davies was himself designated as an expert and the Court struck his testimony on the basis of untimely disclosure by the plaintiffs. He was going to provide the estimate Dr. Keyes is now going to testify to.

We believe it's not proper for Dr. Keyes to testify to this estimate from Dr. Davies since his testimony was stricken.

THE COURT: Ms. Hardin.

MS. HARDIN: We would move to strike the

references to the peer-reviewed article that she has just discussed for the reasons that Mr. Hester has stated. We don't have it. She's not relied on it previously. It's not in her report. And it shouldn't be part of what the Court considers in this case.

MS. MCCLURE: Join both of those, Your Honor.

THE COURT: How, how significant to her testimony is this peer-reviewed study?

MR. FARRELL: None.

THE COURT: Well, then, I'm going to grant the motion to strike.

MR. FARRELL: Thank you.

BY MR. FARRELL:

Q. So let's simplify this. Todd Davies is a Ph.D. at Marshall University; correct?

A. That's what I understand.

Q. And he produced materials in this litigation. Agreed?

A. Yes.

Q. And you relied upon that or reviewed that in your materials?

A. I did.

Q. It's listed in your reference materials?

A. Yes.

Q. And did you cross-reference your findings in Figure 13 --

THE COURT: Mr. Hester.

MR. HESTER: We requested the underlying data on which Dr. Davies relied for this affidavit that Dr. Keyes is going to testify to and we were denied access to the underlying data.

It's not -- we have a hearsay problem. We have a problem that this -- he was going to be testifying as an expert himself on these estimates and the Court struck that testimony. This is now a back-door way into something that the Court's already stricken and it raises a significant hearsay issue.

THE COURT: Well, here again, this is not that significant for her testimony and her opinions, is it?

MR. FARRELL: No. It's just validation that she is right.

THE COURT: Well, I'm going to sustain the objection to that.

MR. FARRELL: Thank you, Your Honor.

BY MR. FARRELL:

Q. So let's get to the whole reason that we're getting to this ultimate conclusion. Have you been able to, to a reasonable degree of epidemiological certainty, been able to determine the prevalence of opioid use disorder in Huntington/Cabell County for the most recent time period?

A. Yes.
Q. Okay. And, so, what is the most recent time period?
A. In this it's 2018.
Q. So as of 2018, what was -- what do you estimate to be the prevalence of opioid use disorder in Huntington/Cabell County, West Virginia?
A. 8.9 percent which I believe is reflective of about 8,200 people in the county who have opioid use disorder.
Q. That would be Cabell County, West Virginia?
A. Yes.
Q. Now, these graphs that we've been showing, these figures that are in your report, the time range for most of them is from 2006 to 2018. Is there anything significant about that time range?
A. No. Sometimes we -- it's based on data available or other times it's just wanting to capture the most recent trend.

THE COURT: You had no data after 2018; is that --

THE WITNESS: We now do. But at the time I submitted the report, we did not.

BY MR. FARRELL:
Q. Let's go to Figure 16. Do you recognize Figure 16?
A. I do.
Q. And will you tell the Judge -- I'm not even going to try this one. Will you tell the judge what's depicted --

where the data comes from and what your findings are from Figure 16?

A. Sure. So in this graph what I was attempting to capture is if you take the number of people who died of an opioid overdose in Cabell County, how many of them are attributable to prescription opioids.

So you've got some people who don't have any history of prescription opioid use. And, so, that death wouldn't be attributable to prescription opioids.

So I wanted to develop some estimates using reliable epidemiological methods to provide some kind of estimate of that attribution. And, so, I went through it really in two steps.

The first is that the most well-accepted and reliable methodologies that we use in epidemiology is to use what's on the death certificate. And, so, if a prescription opioid was listed on the death certificate as a cause of the death at the time of the death, I consider that to be directly attributable to prescription opioids.

So that's what that red line is. Wait. No. Sorry. That's all opioid deaths. The green line is deaths that are directly attributable to prescription opioids. And each of those numbers is an actual number of deaths in the graph.

So, for example, in the most recent 2018, 45 deaths in Cabell County had a record of prescription opioids

contributing to the cause of death.

And then you have the people that don't have a prescription opioid directly contributing as a cause of death. But some of those are attributable to prescription opioids too because as we know from the literature, prescription opioid use is the biggest cause of subsequent other opioid use.

So I used epidemiological data to come up with an estimate of the proportion of people in West Virginia across these years who used prescription opioids before other opioids.

And I used that estimate as an estimate of the number of the overdose deaths that are indirectly attributable to prescription opioids because these are people who more likely than not started their opioid using trajectory with prescription opioids.

So, for example, in 2018, 45 people directly had a prescription opioid listed as a cause of death. Another 20 people indirectly had prescription opioids contributing to their death, by my estimate, because they more likely than not started their trajectory of opioid use with a prescription opioid.

Now, there's one additional wrinkle that I should mention in this graph which was what to do with the synthetic opioid deaths because some of them are going to be

prescription opioids. Some of them are going to be illicit fentanyl. And the death certificate doesn't tell you which is which.

So to estimate how many of those deaths are directly attributable to prescription opioids versus indirectly attributable, I came up with an estimate of the pre-illicit fentanyl time period how many deaths there are in Cabell County that are just based on T40.4 which is the T code in the death certificate for synthetic opioids. And it's about three.

So three people per year in Cabell County prior to the increase in illicit fentanyl died because of exposure to a synthetic opioid, most likely a prescription synthetic opioid.

So I assumed that after the increase in illicit fentanyl, probably about three people a year were still dying of a prescription synthetic opioid overdose, and the remaining T40.4, or synthetic opioid deaths, were due to illicit fentanyl.

So three people per year who had the T40.4 on their death certificate who didn't have another prescription opioid, which a lot of them did, but if they didn't have any other prescription opioid and they just had T40.4, three of them I said, okay, I feel pretty confident that about three are directly attributable to prescription opioids.

And of the remainder, I used that same estimate of the relationship between prescription opioid use and subsequent non-prescription opioid use to apply the indirectly attributable to opioid category.

Q. So you're saying this is reliable?

A. Yes.

Q. And that you believe it's true and accurate?

A. Yes.

Q. And it's based on epidemiology principles and methodology?

A. It is.

Q. A couple more questions. For purposes of the record, you, you mentioned that your paper recites a number of articles. Do you also rely upon the Cerda article, C-e-r-d-a?

A. I do.

Q. And the Dunn article, D-u-n-n?

A. Yes.

Q. And the Hall article?

A. Yes.

Q. And the Muhuri, M-u-h-u-r-i?

A. Yes.

Q. And Inciardi, I-n-c-i-a-r-d-i?

A. Yes.

Q. And the McCabe article?

A. Yes.

Q. That's M-c-C-a-b-e?

A. That's right.

Q. And Vowles, V-o-w-l-e-s?

A. Yes.

Q. And Schieber, S-c-h-i-e-b-e-r?

A. Yes.

Q. And Lankanau, L-a-n-k-a-n-a-u?

A. Yes.

Q. And these -- what do you rely on them for? What proposition do they support?

A. They support various propositions, all, I would say, under the rubric of the criteria that I've used to arrive at causal conclusions from the body of literature.

Q. Dr. Keyes, do you have an opinion whether opioid supply or oversupply is a substantial factor in opioid-related harms including opioid addiction, abuse, morbidity, and mortality?

A. Yes.

Q. And what is that opinion?

A. My opinion is that the opioid supply and oversupply is causally related to the opioid-related harms.

Q. And you believe it's a substantial factor?

A. Yes.

Q. And does that include being a substantial factor in

opioid use disorder in Huntington/Cabell County?

A. Yes.

Q. And in overdoses in Huntington/Cabell County?

A. Yes.

Q. And in Neonatal Abstinence Syndrome?

A. Yes.

Q. And in hospitalizations?

A. Yes.

Q. And in blood-borne diseases such as endocarditis, HIV, and hepatitis?

A. Yes.

Q. And in mortality within fatal overdoses?

A. Yes.

Q. And do you have an opinion whether prescription opioid use is a substantial factor to the initiation and subsequent use of heroin?

A. I do.

Q. What is that opinion?

A. My opinion is that it is a substantial factor.

Q. So to make this as clean and simple as possible, is it your opinion to a reasonable degree of epidemiological certainty that there is a causal association between an increase in exposure to prescription opioids and the related harms that you testified to today?

A. Yes. I believe that the epidemiological literature and

the consensus in my field is very aligned and consistent in demonstrating that it is a causal relationship.

Q. And a substantial factor?

A. And a substantial factor.

MR. FARRELL: Judge, can I have a moment?

THE COURT: Yes.

(Pause)

MR. FARRELL: Judge, we pass the witness.

THE COURT: Now, Mr. Hester.

MR. HESTER: Your Honor, I'm ready to start. I mean, if --

MR. FARRELL: Judge, I would -- excuse me. I'm sorry.

MR. HESTER: Go ahead.

THE COURT: Well, there was some discussion about pulling the plug at this point, wasn't there, so --

MR. FARRELL: That's a great idea, Judge.

MR. HESTER: I'm happy, I'm happy to pull the plug if the Court doesn't mind, but I also am cognizant that we've been making a point that there's pressure on the trial time and we wouldn't want this to somehow count against us. We're trying to hold to the schedule.

THE COURT: Well, I was informed you've got to go to Columbus.

MR. HESTER: I do. But, Your Honor, I can, I can

go a little later.

THE COURT: It's a long way from here and it's --

MR. FARRELL: Judge, we'll make it simple. We'll take the time on us and, and we won't be complaining about it.

MS. KEARSE: Cabell County.

THE COURT: Well, Dr. Keyes is going to have to come back anyway, obviously, because cross examination won't be completed in the next 45 minutes.

So I'm going to ask you to come back, be here at 9:00 Monday morning, Dr. Keyes, and we'll proceed with giving the attorneys for the defendants a shot at you. And I hope you enjoy the weekend.

THE WITNESS: Thank you.

THE COURT: All right. Is there anything else to take up before we quit?

MR. HESTER: Thank you, Your Honor. Have a good weekend.

THE COURT: All right. I'll see everybody at 9:00 Monday morning.

(Trial recessed at 3:18 p.m.)

CERTIFICATION:

I, Ayme A. Cochran, Official Court Reporter, and I, Lisa A. Cook, Official Court Reporter, certify that the foregoing is a correct transcript from the record of proceedings in the matter of The City of Huntington, et al., Plaintiffs vs. AmerisourceBergen Drug Corporation, et al., Defendants, Civil Action No. 3:17-cv-01362 and Civil Action No. 3:17-cv-01665, as reported on June 11, 2021.

S\Ayme A. Cochran
Reporter

s\Lisa A. Cook
Reporter

June 11, 2021
Date

B

C

F

M

Q

R

S

T

U

V

W

X

Y